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[54] ROTATABLE ATTACHMENT MECHANISM FOR ATTACHING A MEDICAL OBSTRUCTION TREATMENT DEVICE SUB-ASSEMBLY TO A DRIVE MOTOR UNIT

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[51] Int. Cl.⁷ **A61B 17/32**

[52] U.S. Cl. **606/170; 606/180**

[58] Field of Search 606/170, 171, 606/172, 173, 180; 15/28, 167.2, 179

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Primary Examiner—Michael Buiz

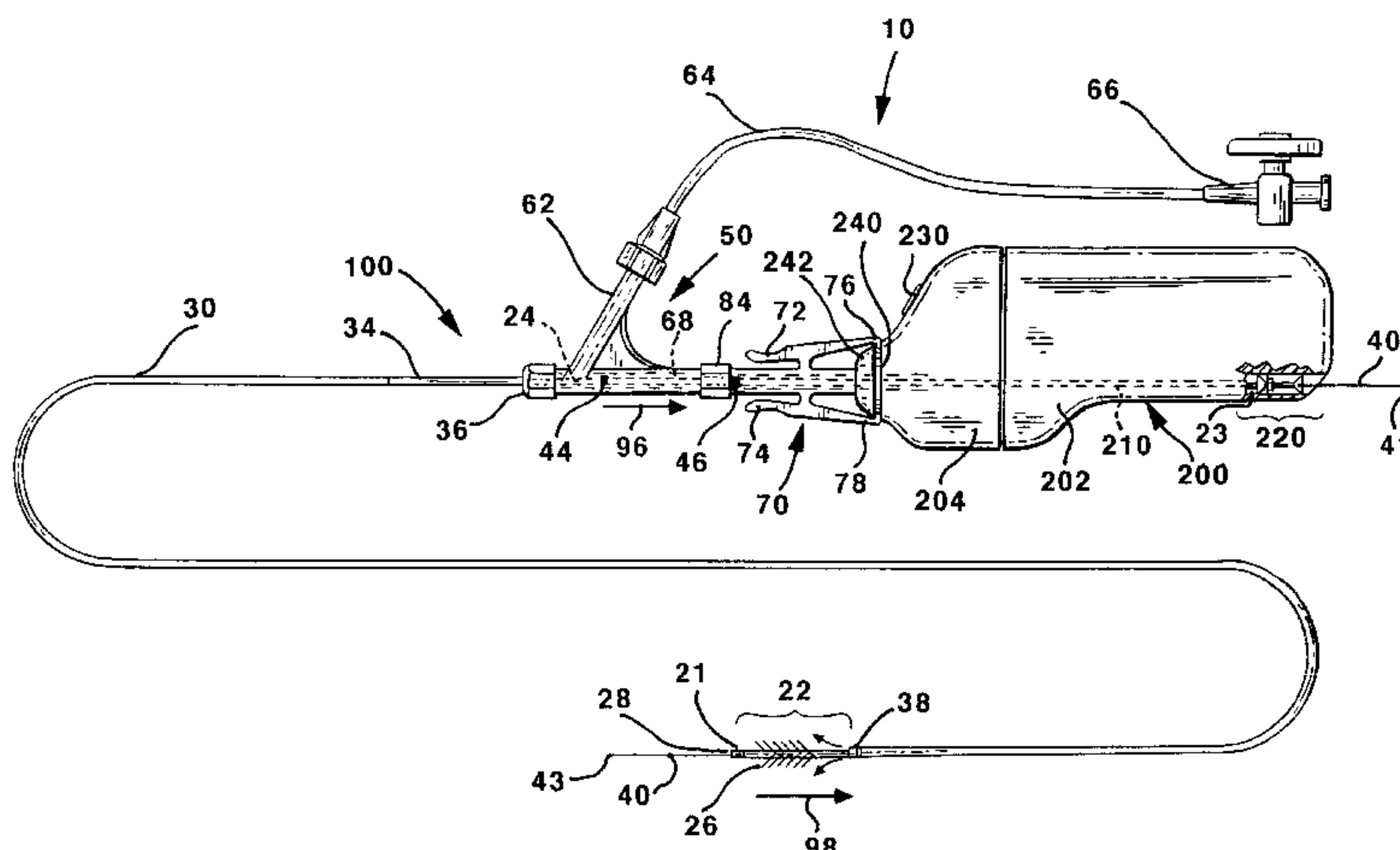
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[57] ABSTRACT

A miniaturized obstruction treatment device, e.g., a resilient brush, particularly adapted for medical use formed at the distal end of an elongated brush drive shaft having a hollow lumen formed therein for introduction over a guidewire. The brush drive shaft is enclosed in the lumen of a brush delivery catheter, and the brush is adapted to be garaged in a distal end section of the brush delivery catheter lumen. A Y-connector and a brush sub-assembly connector are attached to the proximal end of the brush delivery catheter and form a brush sub-assembly with the brush drive shaft and brush. The Y-connector allows infusion of thrombolytic agents into the brush delivery catheter lumen for emission at the distal end opening thereof adjacent the brush. In use, the brush sub-assembly connector connects the brush sub-assembly with a drive motor unit connector of a drive motor unit. The drive motor unit receives the proximal end of the drive shaft and rotates it to rotate the brush bristles. The brush and brush drive shaft distal section are automatically extended out of the catheter lumen distal end opening when the sub-assembly connector and the drive motor unit connector positively lock together. Simultaneously, a drive hub of the brush drive shaft locks into a drive chuck of a drive motor unit to enable rotation of the drive shaft, and the drive shaft proximal end is seated in a dynamic seal that inhibits infiltration of blood and thrombolytic agent into the drive motor housing.

26 Claims, 14 Drawing Sheets



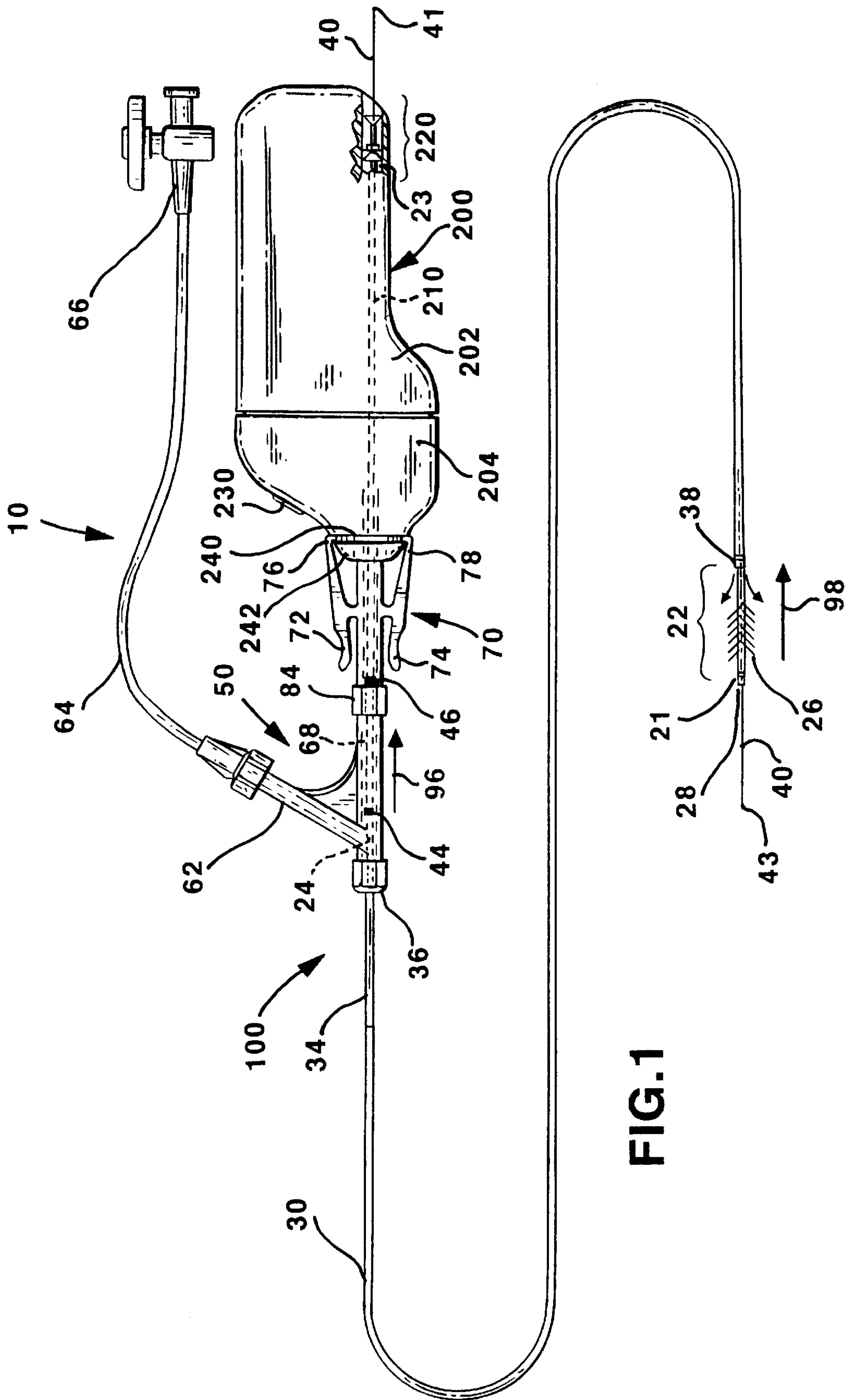


FIG. 1

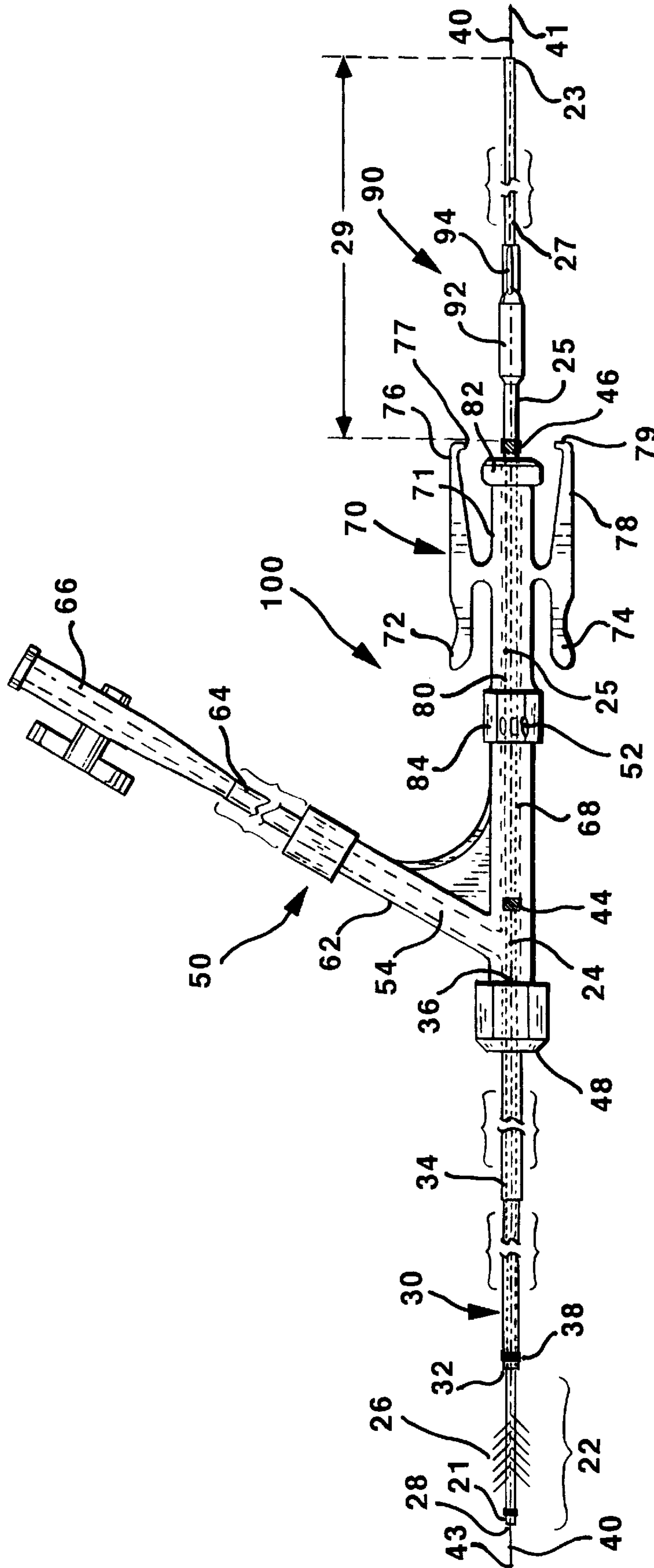


FIG. 2

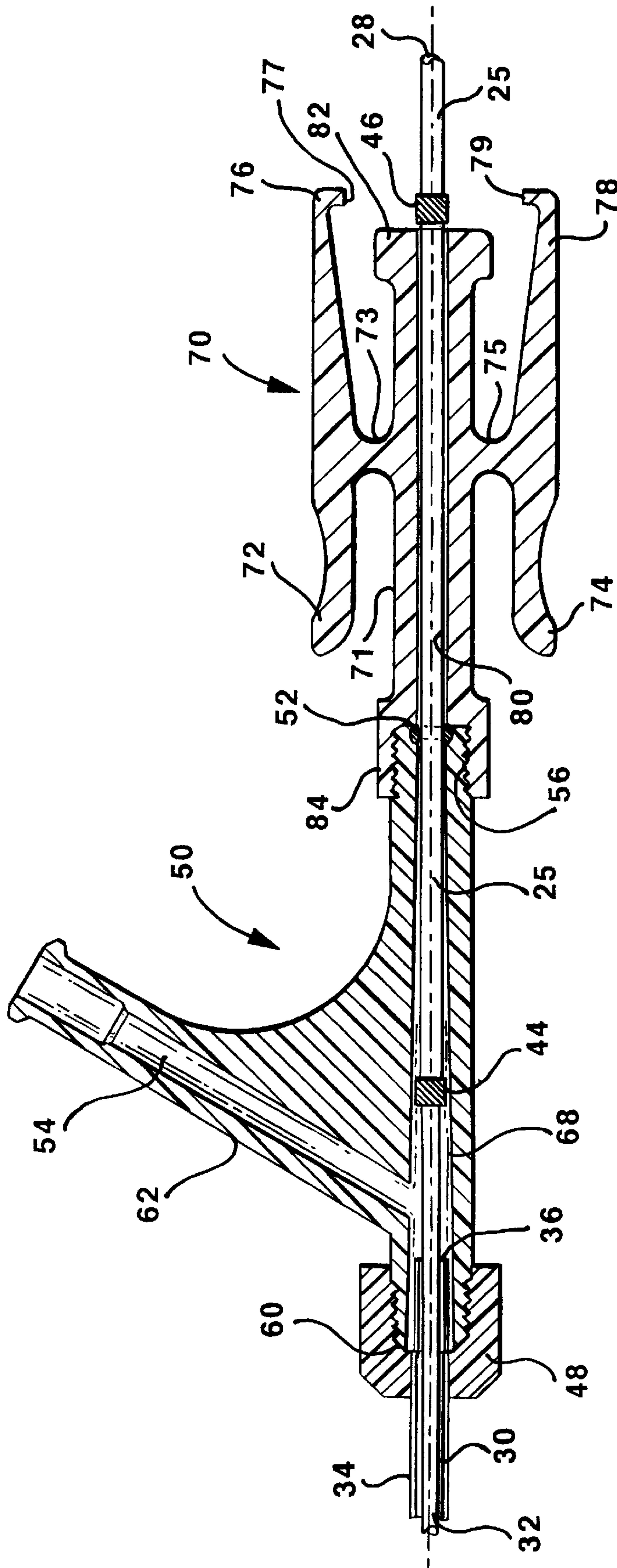


FIG. 3

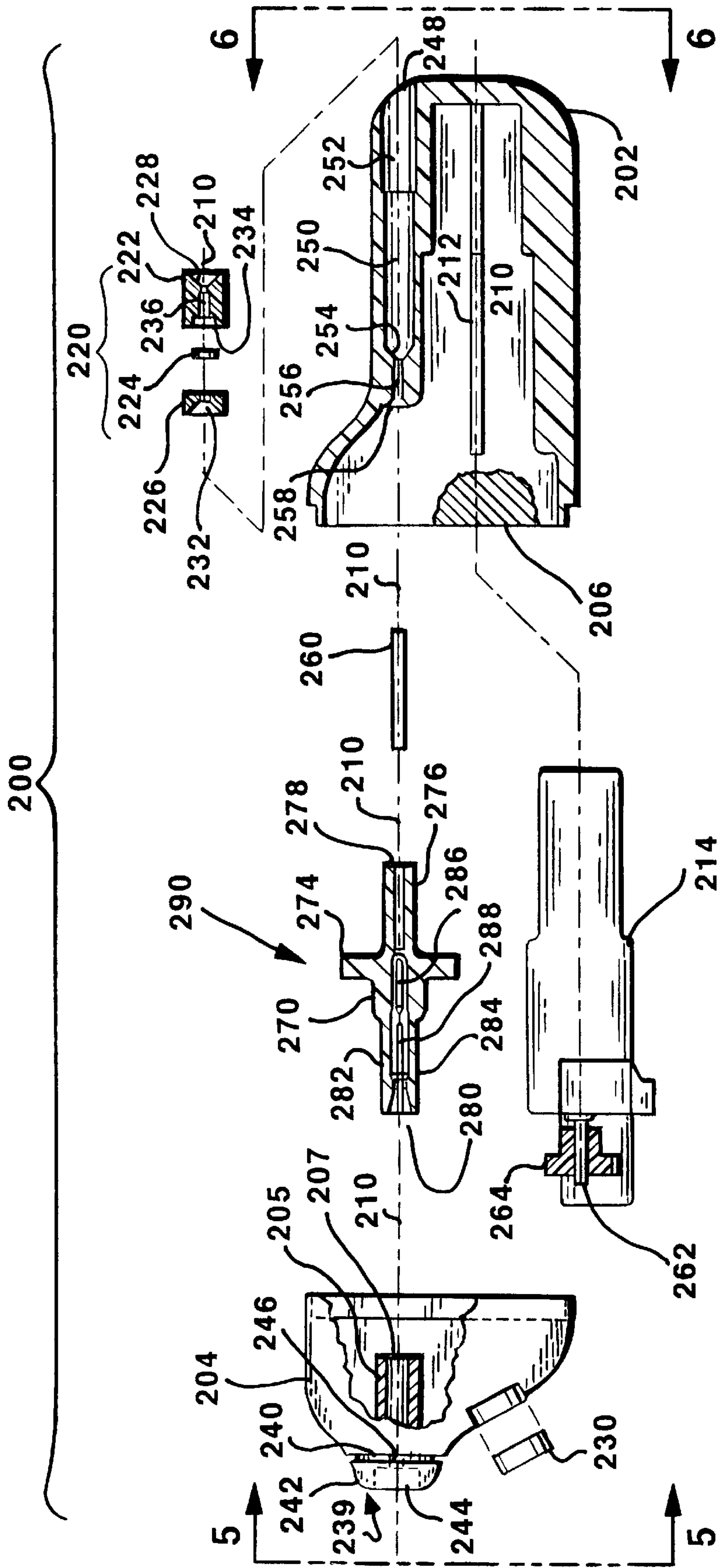


FIG.4

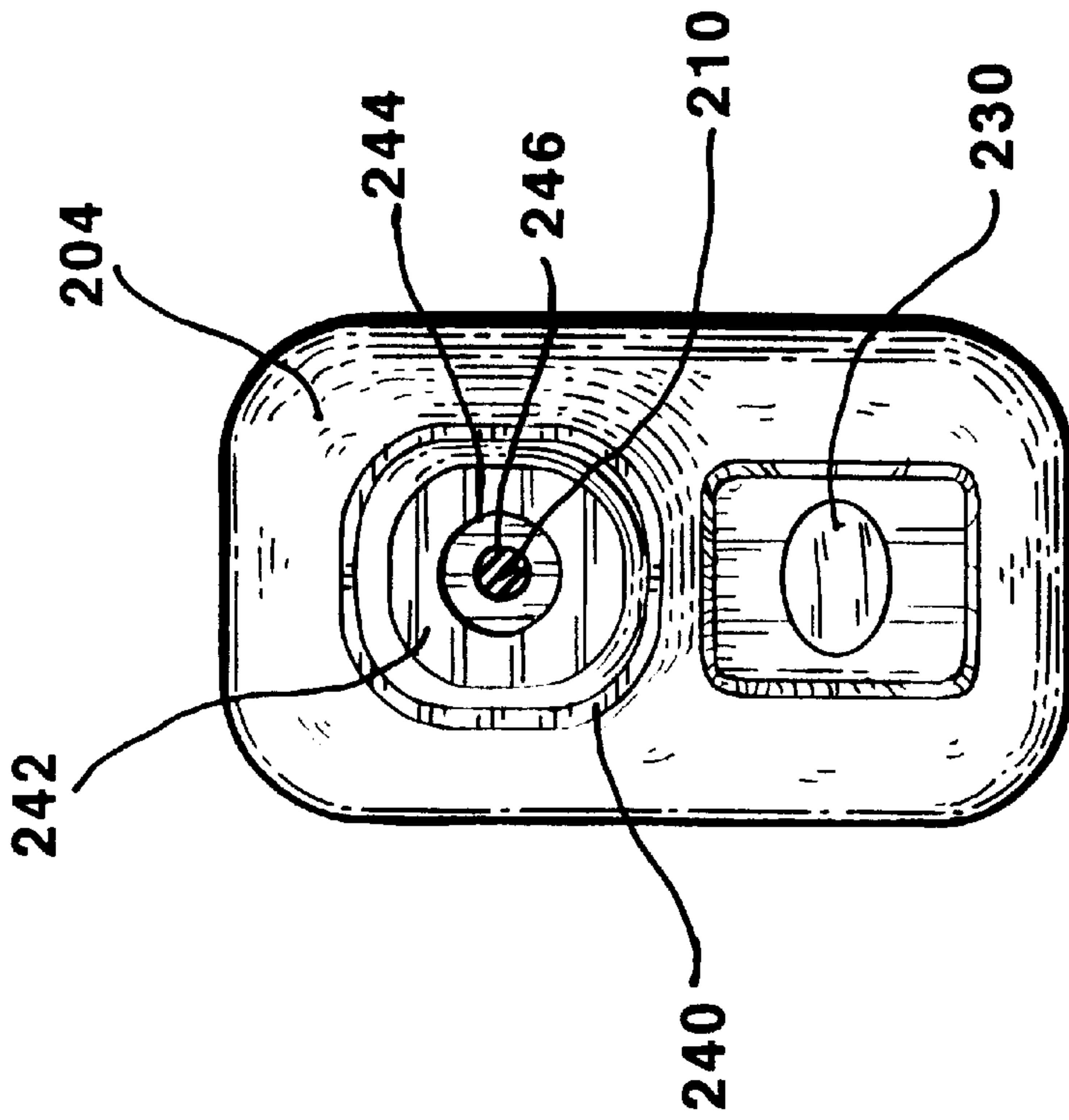


FIG. 5

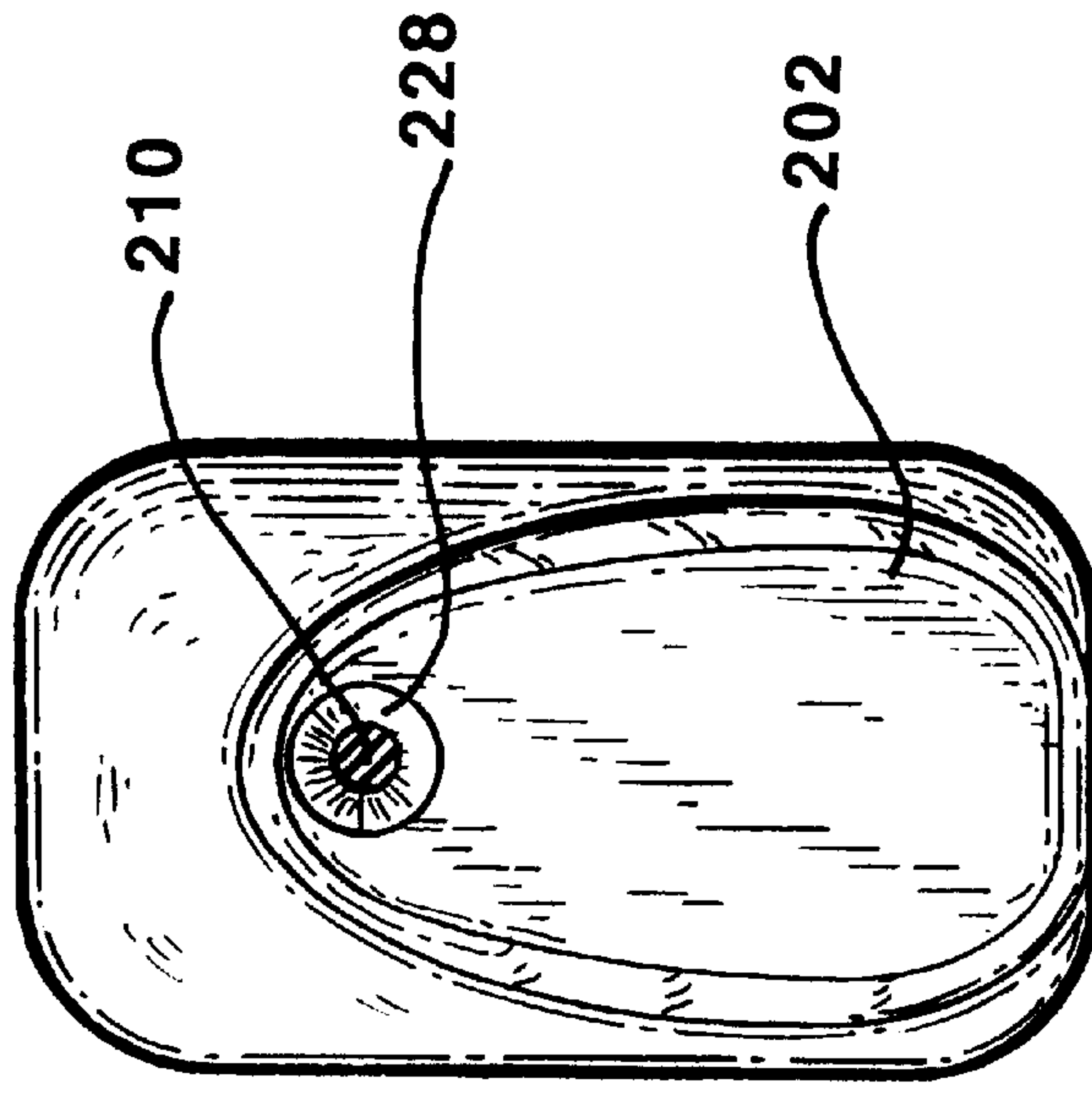


FIG. 6

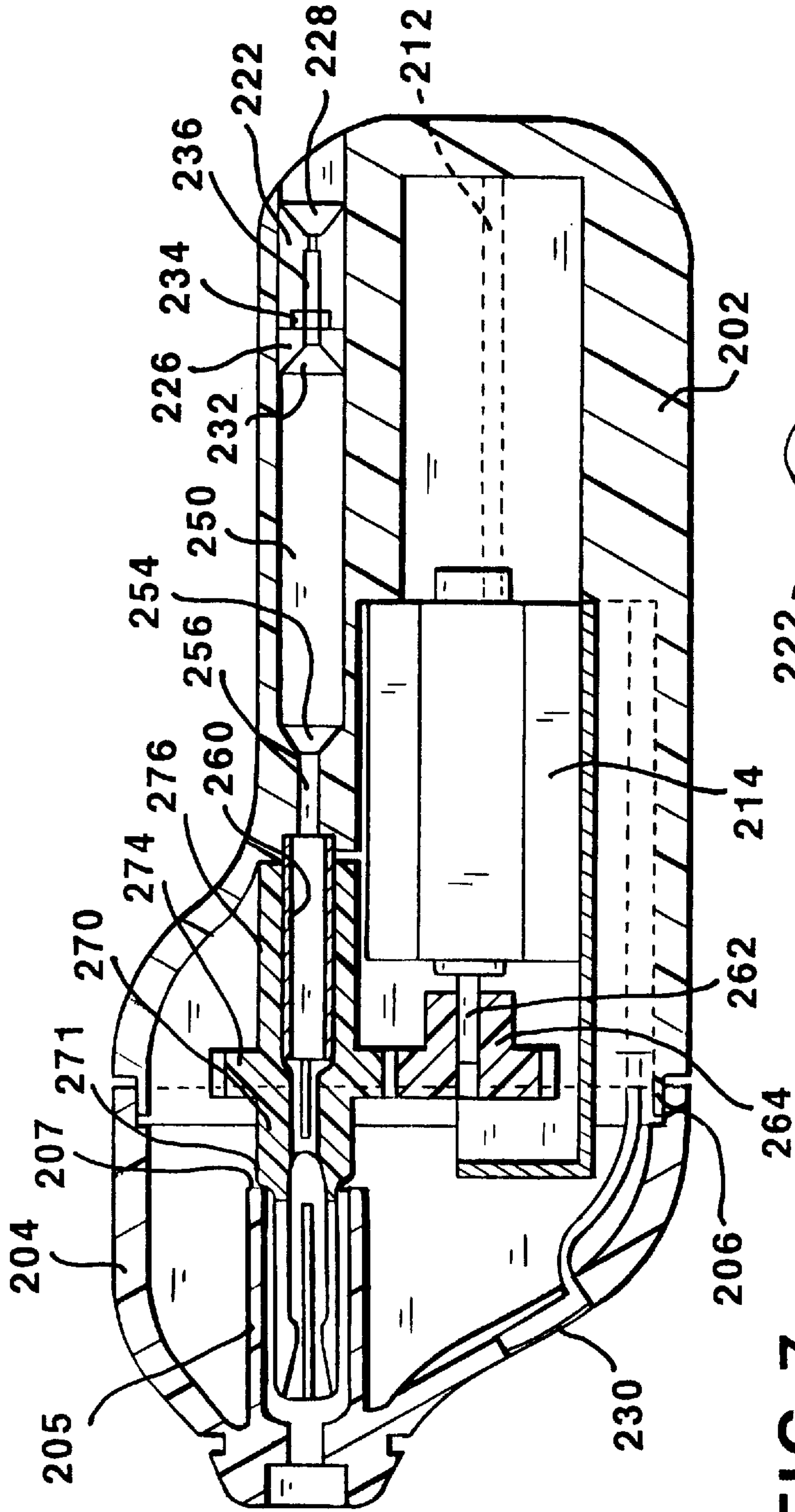


FIG. 7

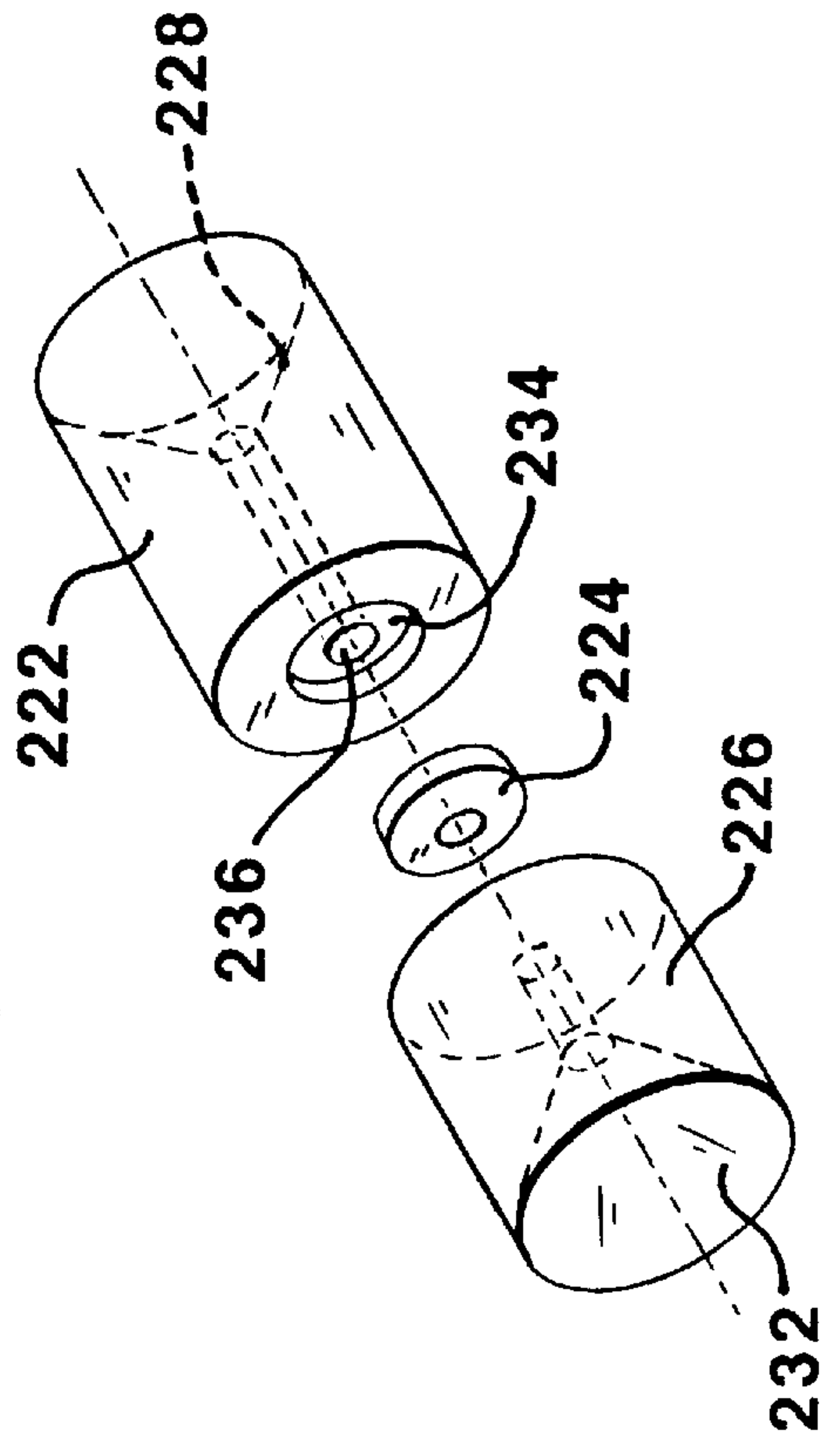


FIG. 8

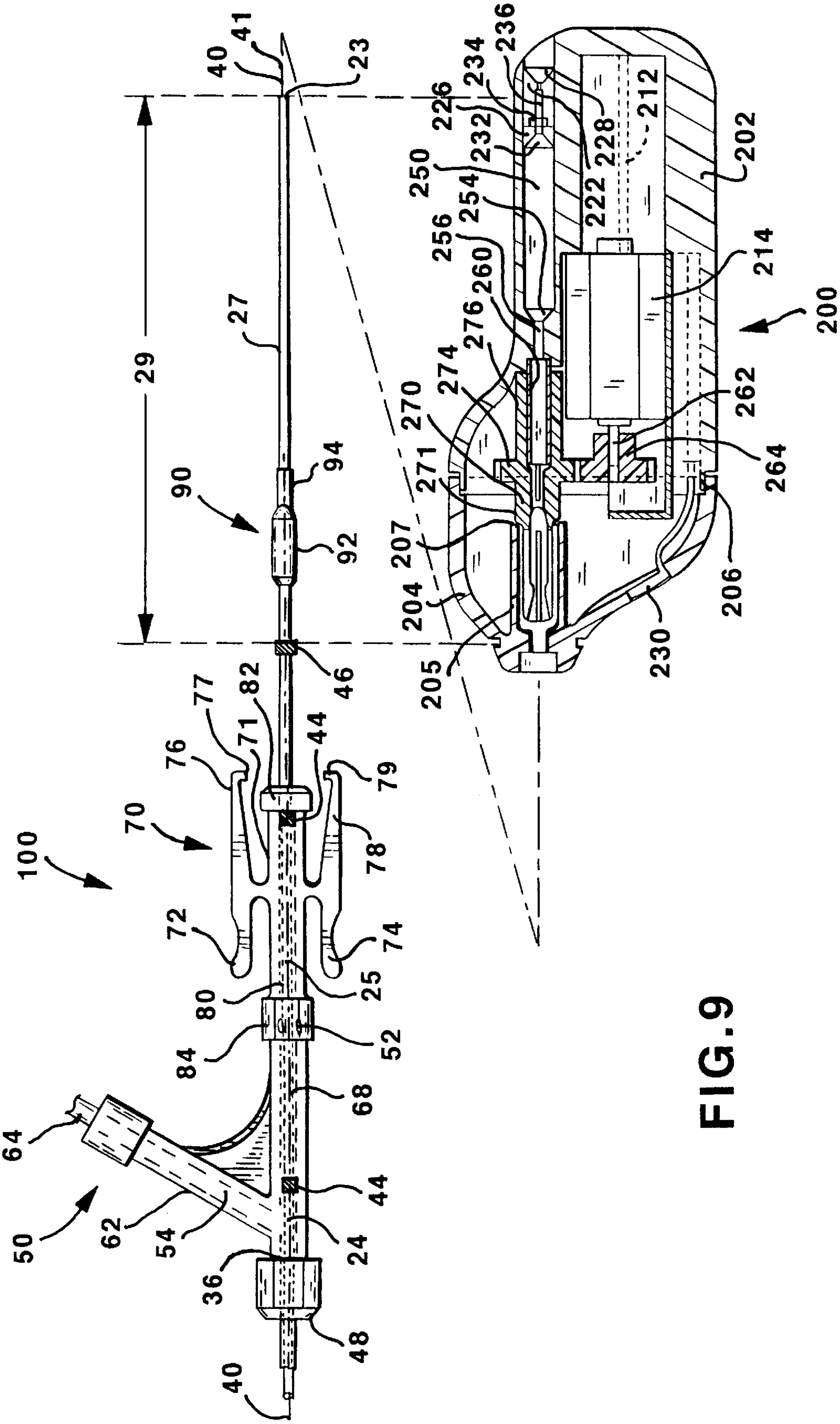


FIG. 9

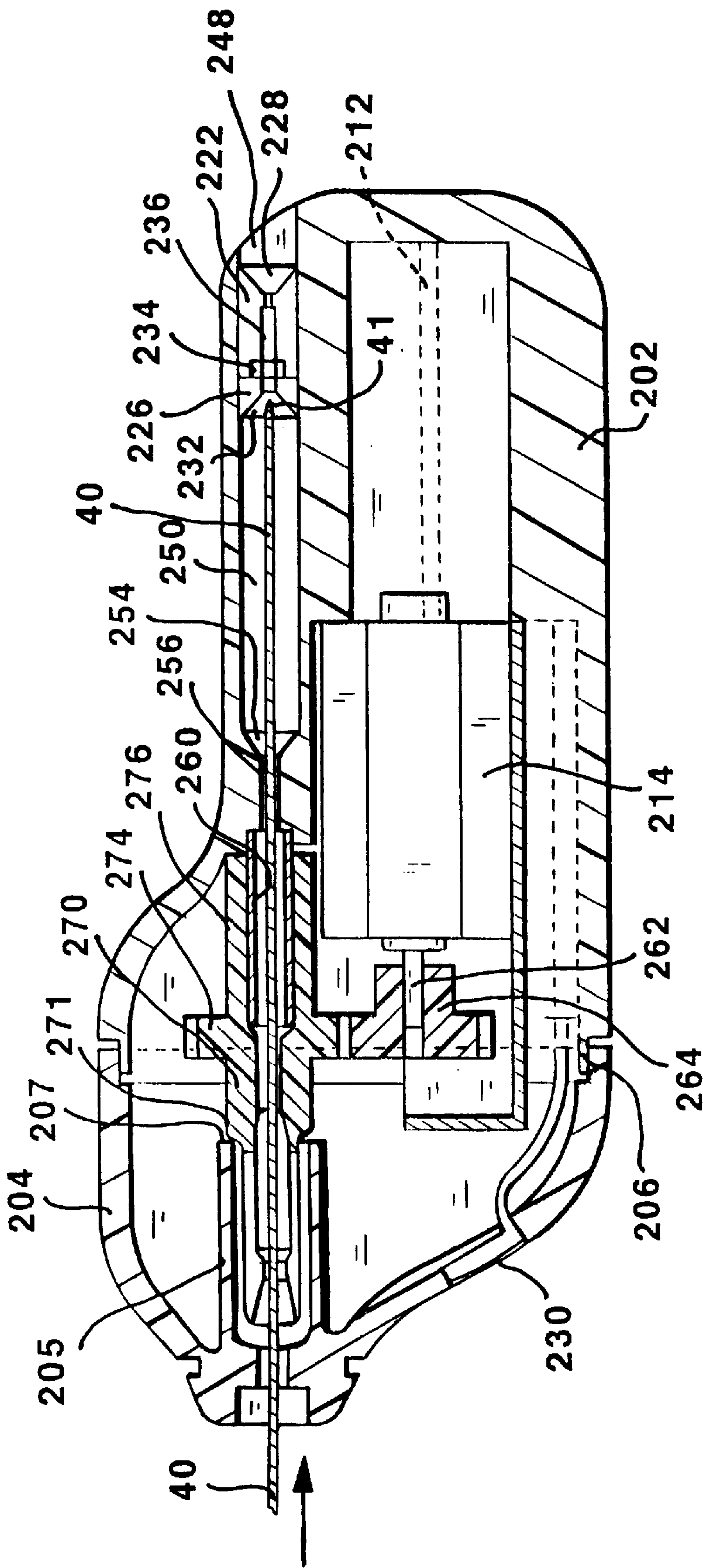


FIG. 10

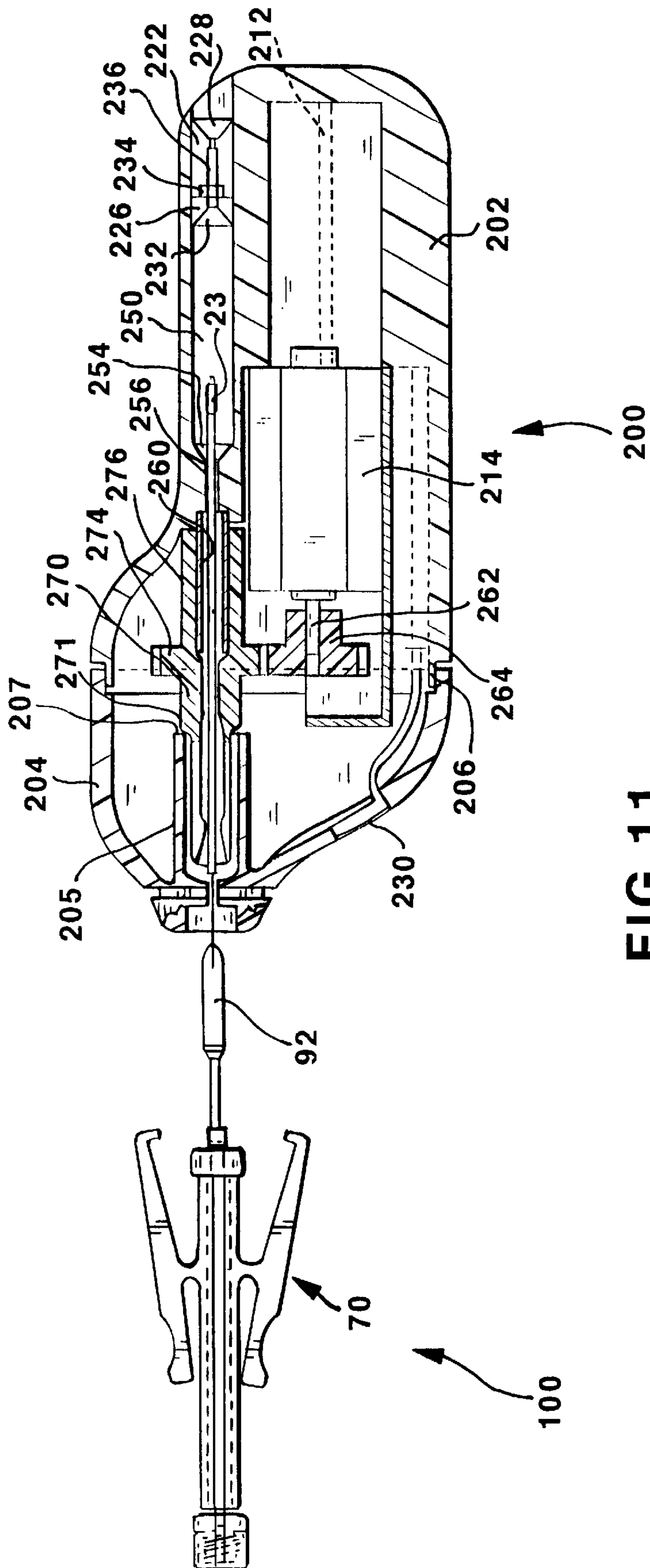


FIG. 11

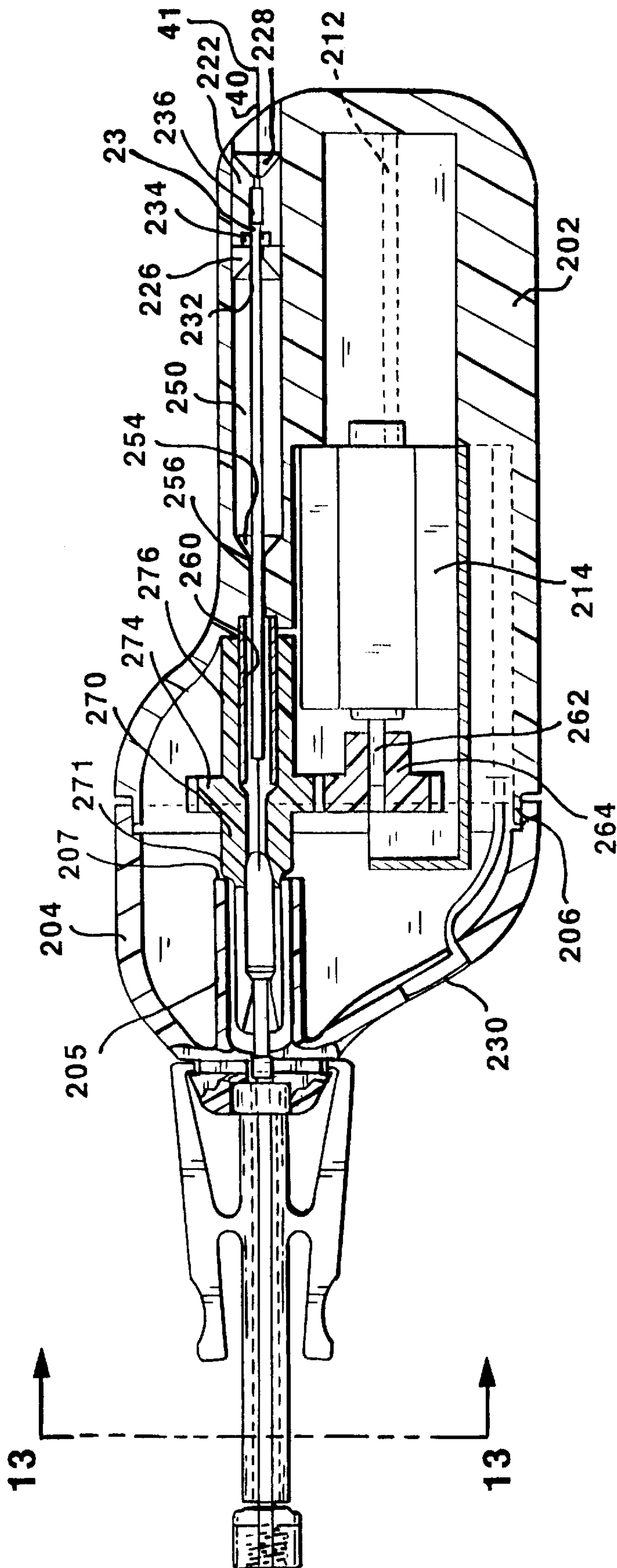


FIG.12

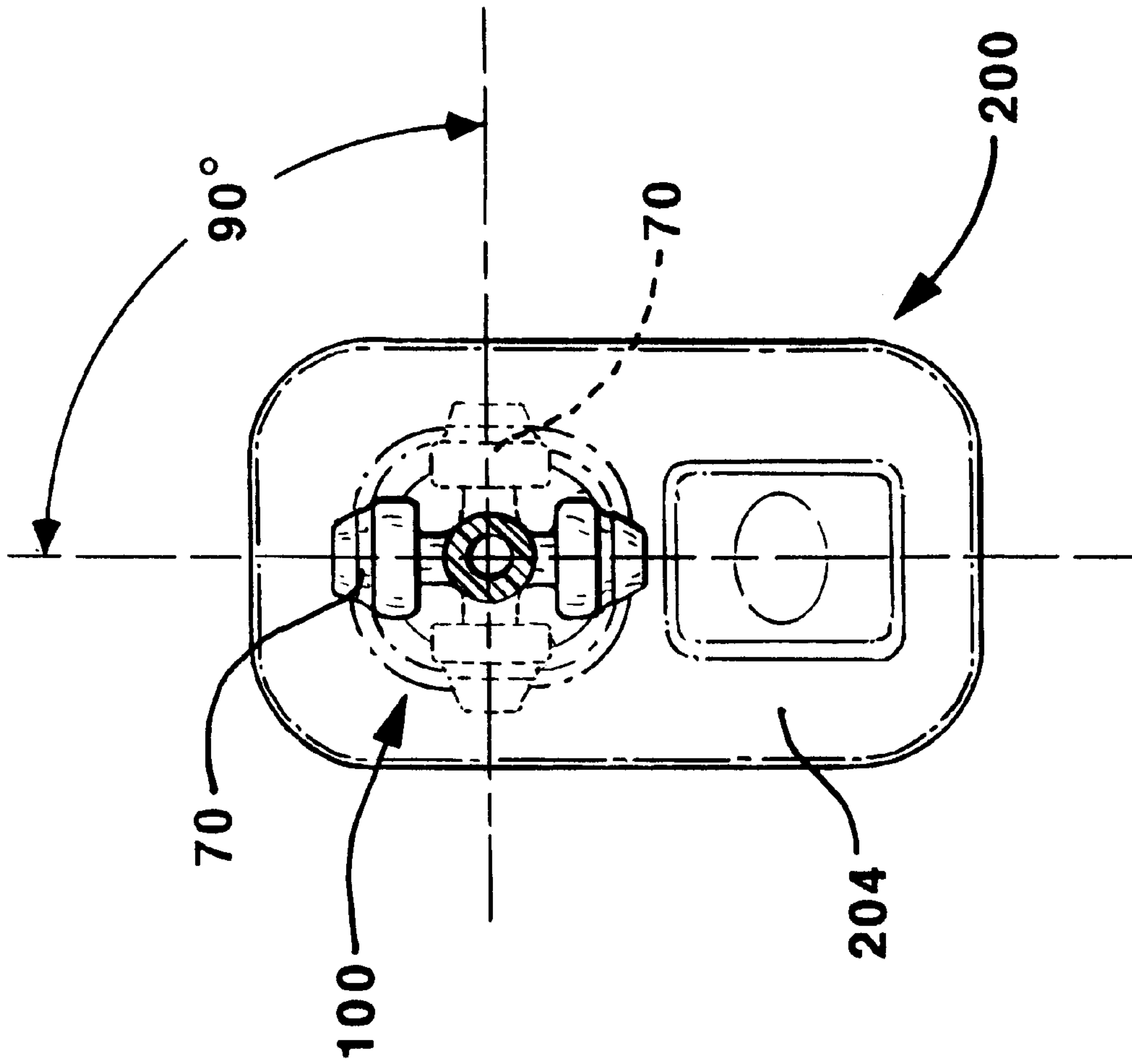


FIG. 13

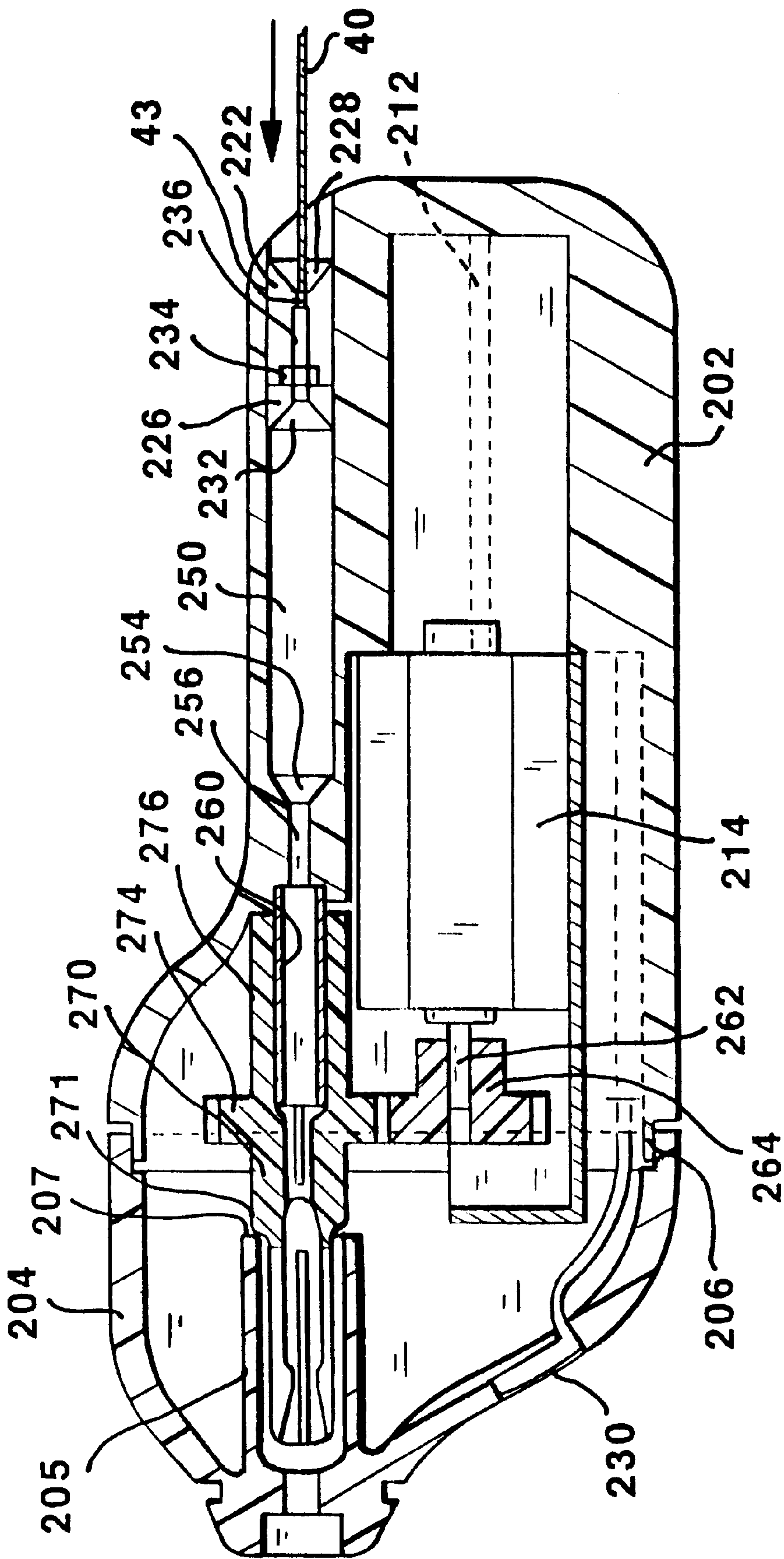


FIG. 14

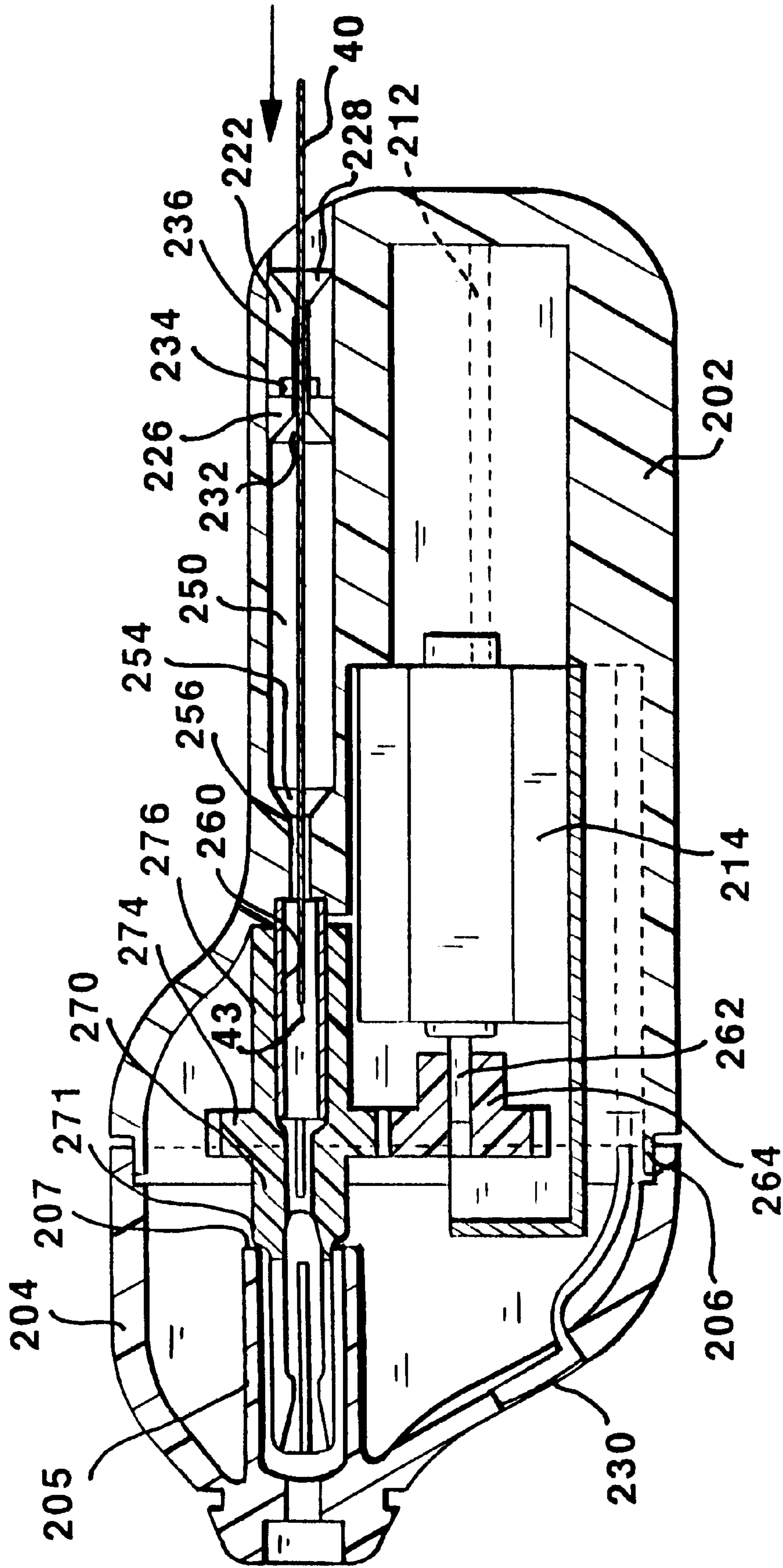


FIG. 15

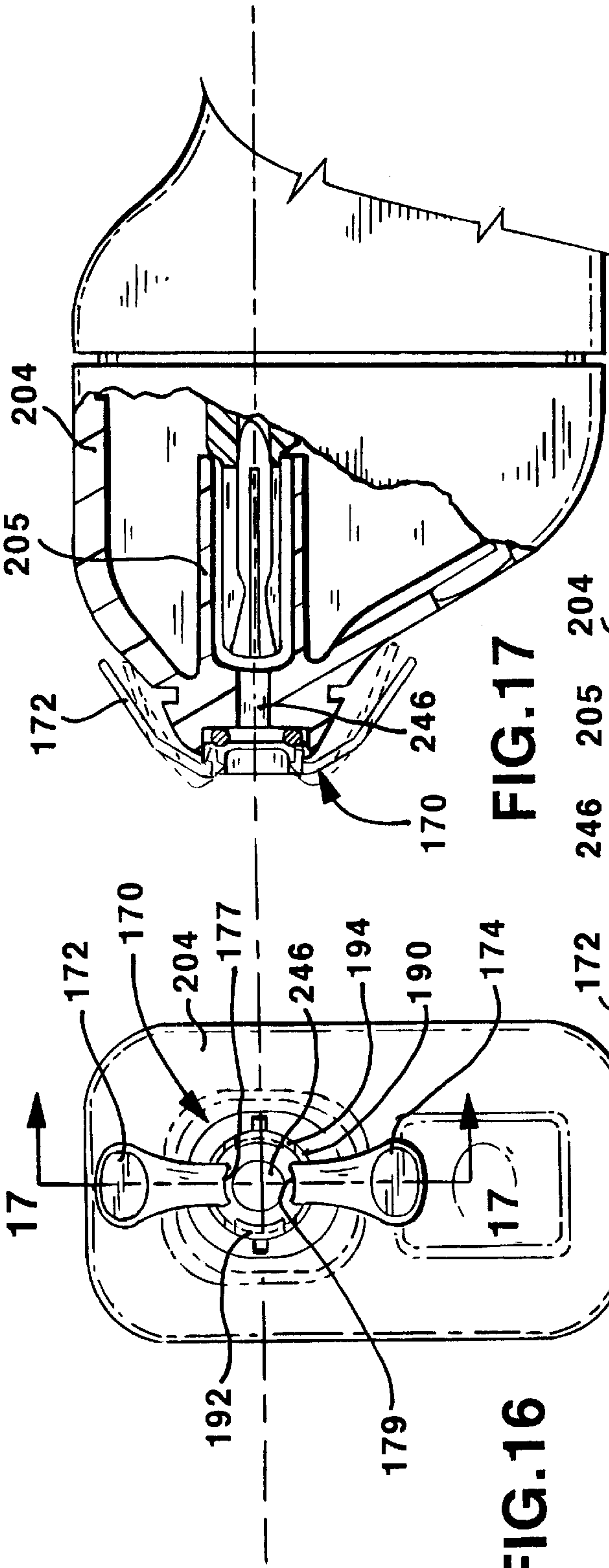


FIG. 17

FIG. 16

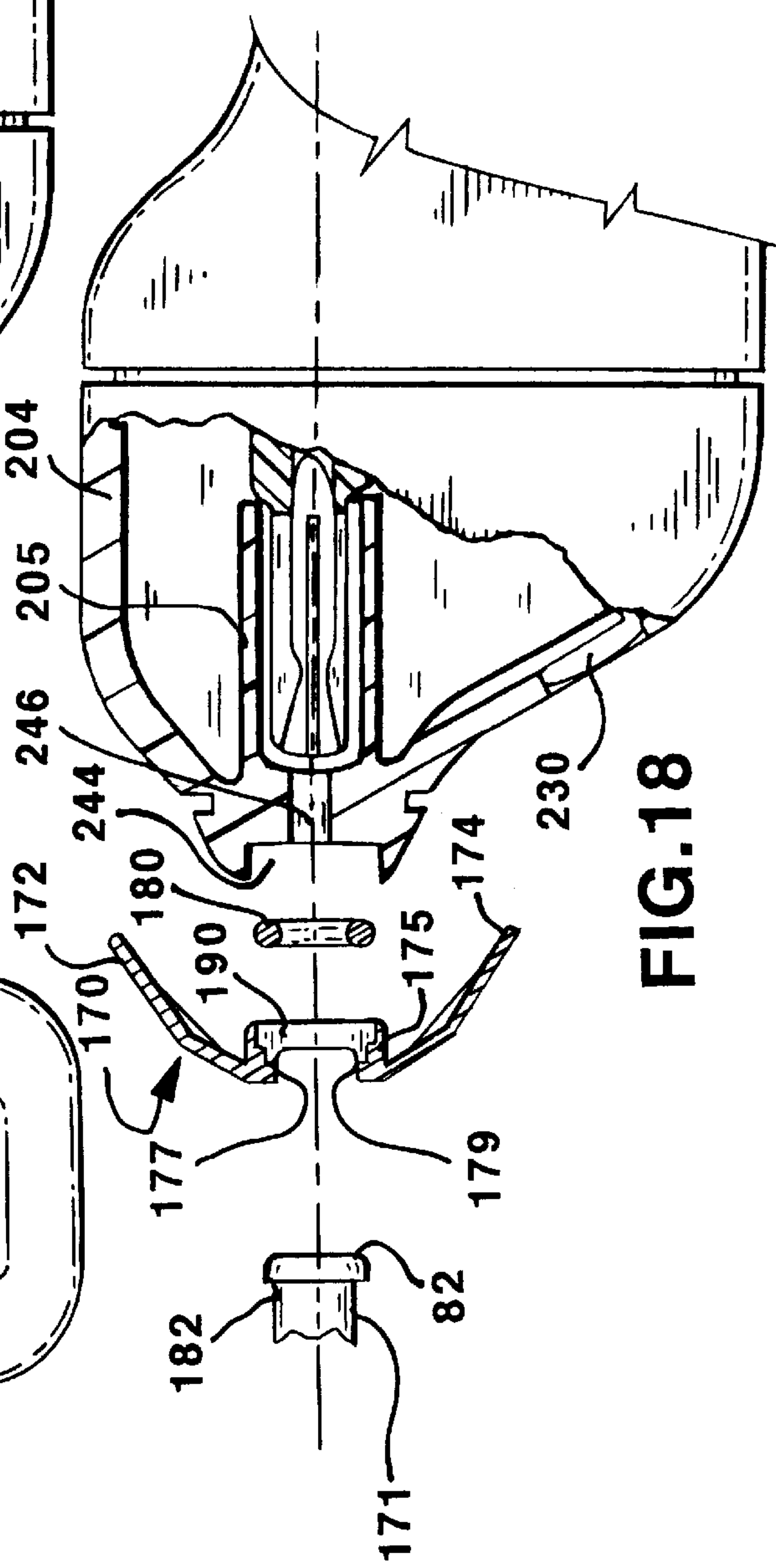


FIG. 18

**ROTATABLE ATTACHMENT MECHANISM
FOR ATTACHING A MEDICAL
OBSTRUCTION TREATMENT DEVICE SUB-
ASSEMBLY TO A DRIVE MOTOR UNIT**

**CROSS-REFERENCE TO RELATED
APPLICATIONS**

Reference is hereby made to commonly assigned, co-pending U.S. patent application Ser. No. (9135390.APP) filed on even date herewith for MINIATURIZED MEDICAL BRUSH in the names of Richard R. Monetti et al. and Ser. No. (9135410.APP) filed on even date herewith for ROTATABLE DYNAMIC SEAL AND GUIDE FOR A MEDICAL OBSTRUCTION TREATMENT DEVICE SUB-ASSEMBLY COUPLED TO A DRIVE MOTOR UNIT in the names of Blair D. Walker et al.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to attachment of a drive motor unit to a medical obstruction treatment device sub-assembly, and more particularly to a rotatable attachment mechanism for attaching a medical brush sub-assembly comprising a brush at the distal end of a brush drive shaft and enclosed within a brush delivery catheter, to a drive motor unit.

2. Description of the Background Art

Commonly assigned, U.S. Pat. No. 5,370,653 to Cragg, incorporated herein by reference in its entirety, discloses a thrombectomy system for dissolving a soft fibrinous obstruction, such as a recently formed thrombus, within a patient's vascular system, either in a patent vein or artery or in a vascular implant, e.g. an A/V graft. The thrombectomy system employs rotating brush bristles within the thrombus to separate the fibrin of the thrombus from blood cells while mixing the separated fibrin with a dissolving or thrombolytic agent, e.g. streptokinase or urokinase, that is introduced at the same time into the separated fibrin.

Commonly assigned U.S. Pat. No. 5,681,355 to Serra et al., incorporated herein by reference in its entirety, discloses a hollow lumen, thrombectomy brush and method of fabrication which allows for the brush to be introduced over a previously placed guidewire into a very small blood vessel. The miniaturized brush is provided with an elongated, flexible, rotatable brush or drive shaft adapted to be attached at its proximal end to a drive motor for rotating the shaft. The drive shaft is formed with a proximal elongated section formed of a hollow, thin wall tube having an inner lumen and an outer surface and a distal section. The brush is formed of brush filaments, each having first and second ends and a predetermined length between the first and second ends, entrapped in a winding interface between turns of the coiled wire and the outer wall of the hollow tube extension in an entrapment zone intermediate the first and second ends.

The inventive rotating brush described in the '653 patent has flexible brush bristles extending outward from a brush shaft or drive shaft distal end in all directions. The brush is attached to the elongated, flexible, rotatable drive shaft or brush shaft which is attached at its proximal end to a drive motor to impart rotary motion to the brush shaft and bristles. The system includes a brush delivery catheter adapted to be introduced and advanced through a patient's blood vessels until the distal end is positioned adjacent the soft fibrinous thrombus. Once the brush delivery catheter is positioned, the brush bristles and brush shaft are passed through the brush

delivery catheter lumen and out its distal opening to place the brush in contact with the soft thrombus. The bristles are sufficiently resilient and dimensioned for allowing compression and passage out of and back into the distal opening of the brush delivery lumen and for mixing into and macerating the fibrin of the soft thrombus, without damaging a vessel wall.

In one embodiment described in the '653 patent, the brush shaft is hollow to define a brush shaft lumen and preferably is formed with a penetrable distal tip valve normally closing the distal end opening of the brush shaft lumen. The thrombolytic agent is optionally delivered through the brush shaft lumen and through side exit holes or ports into the region of the brush bristles. The brush shaft lumen allows the advancement of the brush over a previously introduced and positioned guidewire to a thrombus in a blood vessel or the lumen of a medical implant.

In another embodiment disclosed in the '653 patent, the brush drive shaft is solid, and the dissolving agent is introduced through the brush delivery catheter lumen alongside the drive shaft lumen while the brush drive shaft is rotated. The thrombolytic agent is emitted from the distal end opening of the brush delivery catheter lumen in the region of rotation of the brush bristles for dissolving the soft thrombus exposed by the rotating brush bristles.

The assignee of the '653 and '355 patents and the present application has implemented the solid drive shaft brush embodiment of the '653 patent in the Cragg Thrombolytic Brush™. The Cragg Thrombolytic Brush™ is presently used in the lumen of an A/V graft implanted in a patient's vascular system for hemodialysis to dissolve thrombi that form therein. The Cragg Thrombolytic Brush™ is described and depicted in "The Thrombolytic Brush", by Andrew H Cragg, MD presented at The Second Mid-Atlantic Conference on Angio Access: Establishment and Maintenance of Dialysis and Venous Access, Williamsburg, Va. (pp. 162-165 of proceedings) in October 1996 and in product literature published by the assignee in 1997.

In the Cragg Thrombolytic Brush™ embodiment, the brush and brush drive shaft are enclosed within the brush delivery catheter as a sub-assembly that allows the brush to be garaged in the brush delivery catheter lumen as it is advanced to the graft lumen and to be advanced out of the catheter lumen distal end opening. The brush sub-assembly includes a Y-connector at the proximal end of the brush delivery catheter that has a Y-connector lumen that the brush drive shaft passes through. The Y-connector includes a side port coupled to an infusion port for allowing thrombolytic agent to be introduced into the Y-connector lumen and then distally down the annular space between the brush drive shaft and the brush delivery catheter lumen. The proximal end of the Y-connector includes a seal for sealing around the brush drive shaft to prevent leakage of the infused thrombolytic agent and a threaded luer connector having a proximal luer hub that fits into an annular recess in the housing of the drive motor unit.

An enlarged male shaft hub is formed at the proximal end of the brush drive shaft that is inserted axially through a central opening of the annular recess and into engagement with a female bore aligned with the central opening. The female bore is integrally formed within a driven gear that is rotated by a drive gear coupled with the drive motor. As the shaft hub is seated into the female bore, the brush sub-assembly and the drive motor unit are brought together to fit the luer hub proximal end into the annular recess of the drive motor unit. The drive motor unit and the hub are rotated with

respect to one another to rigidly attach them together. The brush is ejected distally from the brush delivery catheter lumen.

At this point, the brush delivery catheter and brush drive shaft are extended through the patient's vascular system and it is undesirable to rotate them within the vascular system. It is therefore necessary to rotate the drive motor unit while holding the brush sub-assembly still in order to attach the luer lock elements together. It is not always possible to know in advance just how the drive motor unit will be aligned with respect to the side port of the Y-connector when the attachment is finished. Thus, the attachment process and any adjustment has to be done carefully and relatively slowly to arrive at a suitable final attachment orientation.

The drive motor unit is manually grasped by the physician during the medical procedure so that the button can be depressed to energize the motor and so that the motor and brush can be moved back and forth to position the brush in the graft lumen. The rigid attachment can cause the side port of the Y-connector to extend in an awkward direction. The threaded attachment of the male and female luer connector elements can limit the physician's ability to rotate the drive motor unit and the brush sub-assembly to a desired orientation. The tubing that is coupled between the side port and the infusion port coupled with a source of thrombolytic agent can become twisted.

Moreover, the use of the luer lock attachment does not always provide positive feedback that the attachment is correct which can result in imprecise longitudinal alignment of the brush sub-assembly with the drive motor unit. If only a few turns are engaged, the brush at the distal end of the brush drive shaft may be incompletely ejected from the brush delivery catheter or the shaft hub may be incompletely seated into the female chuck. Over tightening of the male and female luer attachment elements can also occur.

In addition, vibration of the drive motor unit when it is operated and manual twisting of drive motor unit and/or the brush sub-assembly can cause the luer lock attachment to loosen, requiring periodic tightening or re-attachment.

These problems are magnified in the context of use of a hollow lumen drive shaft that allows introduction of the brush drive shaft over a previously positioned guidewire as envisaged in one embodiment of the above-incorporated '653 patent. In that context, it is often desirable to connect and disconnect the brush sub-assembly from the drive motor unit. At times during a procedure, it is desirable to remove or insert a guidewire from or into the proximal end opening of the drive shaft lumen while it is separated from the drive motor unit requiring detachment and reattachment of the luer lock elements.

A need exists for a simpler and quicker attachment mechanism that provides repeatable and precise dimensional attachment, positive feedback of attachment, and also allows for rotation of the brush sub-assembly with respect to the drive motor unit to a convenient orientation for accommodating infusate tubing and equipment.

SUMMARY OF THE INVENTION

It is a primary object of the present invention to provide such a simplified, repeatable, precise and positive attachment mechanism for attaching an obstruction treatment device sub-assembly with a drive motor unit.

It is a principal object of the present invention to provide such an attachment mechanism that allows full 360° rotation of the sub-assembly with respect to the drive motor unit.

It is another principal object of the present invention to provide such an attachment mechanism that is adapted to

precisely axially align an obstruction treatment device drive shaft with drive and sealing components of the drive motor unit at any angular orientation of the obstruction treatment device sub-assembly with the drive motor unit.

In accordance with these and other objects, a motor and obstruction treatment device assembly is provided with a rotatable, precise, positive and repeatable attachment mechanism of the sub-assembly with the drive motor unit that is simple to attach and separate. After attachment is made, the brush sub-assembly is rotatable to a desired angular orientation with the drive motor unit without having to release the attachment mechanism.

In accordance with the preferred embodiments of the invention, the hand held drive motor unit is formed with a drive motor lumen for receiving a proximal drive member of a brush sub-assembly inserted into a drive motor lumen distal end opening and a drive motor unit connector. The brush sub-assembly is formed with a sub-assembly connector for making connection with the drive motor unit connector when the proximal drive member is axially aligned with and inserted axially into the distal drive motor lumen opening and seated therein. The sub-assembly connector and the drive motor unit connector positively lock together upon axial insertion and mutual engagement. The mutual engagement of the connectors allows rotation of the brush sub-assembly with respect to the drive motor unit to a selected angular alignment. The mutual engagement of the connectors allows the proximal drive member to be rotated by the drive motor unit at any selected angular alignment of the brush sub-assembly with respect to the drive motor unit.

In one preferred embodiment, the drive motor unit housing is formed with an annular, dome shaped projection surrounding the drive motor unit distal end opening providing a cam surface of increasing diameter radially from the axis of the drive motor unit lumen. The cam surface is maximally bounded by an annular retention groove recessed into the drive motor unit housing. An annular, proximally extending, drive motor unit receptacle is formed within the dome shaped projection that also surrounds the drive motor unit distal end opening. The annular receptacle, the retention groove surrounding the annular receptacle, and the cam surface extending therebetween comprise the drive motor unit connector.

The sub-assembly connector of this embodiment further comprises an elongated tubular barrel surrounding a sub-assembly connector lumen extending through the barrel and terminating at an enlarged annular proximal seat. A pair of moment arms that are hinged to the barrel and project proximally alongside the barrel and to free clip ends thereof. The free clip ends are biased by the hinges to have a pre-determined separation apart from one another that is less than the diameter of the annular retention groove.

The attachment is effected by axially aligning the proximal seat with the annular receptacle and pressing the free clip ends against the cam surface to cause the free clip ends to ride upon the cam surface and to separate apart. The separation continues until the free clip ends slip into the retention groove and lock therein. The barrel can be rotated as the free clip ends slip around the retention groove to thereby rotate the brush sub-assembly with respect to the drive motor unit.

The moment arms also extend distally from their hinges to finger grips located distal to the hinge locations. The hinges are resilient enough to allow the finger grips to be squeezed together toward the connector barrel to increase the separation of the free clip ends until they are released from the retention groove.

In a further embodiment, the drive motor unit connector comprises moment arms that are hinged with respect to the annular proximally extending drive motor unit receptacle. The moment arms extend proximally from hinges to finger grips, and extend to arcuate clips that extend inward into the annular receptacle in the unstressed position of the moment arms. The sub-assembly connector simply comprises a distal rim of the enlarged annular proximal seat of the barrel. The finger grips can be depressed inward toward the drive motor unit housing to move the arcuate clips outward so that the annular proximal seat can be inserted into the annular proximally extending receptacle past them. The arcuate clips engage the distal rim on release of the tension applied to the finger grips. A resilient O-ring is also inserted within the annular proximally extending receptacle to provide a resilient seating engagement with the annular proximal seat of the barrel. The arcuate clips force the annular proximal seat against the O-ring to compress it slightly, and the compressed O-ring tensions the attachment between the arcuate clips and the distal rim.

In both preferred embodiments, the brush sub-assembly comprises a brush mounted to a brush drive shaft, a brush delivery catheter having a catheter lumen receiving the brush drive shaft, and the sub-assembly connector. The sub-assembly connector is coupled with the proximal end of the brush delivery catheter, preferably through an intermediate Y-connector. The sub-assembly connector lumen is aligned with the catheter lumen, preferably through an intermediate Y-connector lumen, for receiving the brush drive shaft. The brush drive shaft is rotatable within the aligned lumens by operation of the drive motor unit.

The elongated, flexible, rotatable drive shaft extends from a proximal drive shaft end to a distal drive shaft end and preferably is formed with a drive shaft lumen extending through its length between lumen openings at the proximal and distal drive shaft ends. An elongated, flexible, distal drive shaft section in which the brush is formed is dimensioned to fit within a catheter lumen of a brush and thrombolytic agent delivery catheter. The proximal drive member is formed in a portion of the drive shaft proximal to the distal drive shaft section and is configured to be received in a drive motor lumen of the drive motor unit. When the proximal drive member is received in and seated in the drive motor lumen, it engages drive components of the drive motor unit for rotating the drive shaft and brush and the proximal drive shaft end is accessible from a proximal drive motor lumen end opening. The proximal drive member is received in and seated in the drive motor lumen when the brush sub-assembly connector and the drive motor unit connector are engaged as described above.

The brush can be retracted proximally into the brush drive shaft lumen when the proximal drive member is not received and seated in the drive motor lumen. The brush can thereby be garaged therein to facilitate introduction of the brush sub-assembly to a site of a soft obstruction. The brush drive shaft can also be manually advanced distally in the same path to distally extend the brush out of the catheter lumen distal end opening. In accordance with a further aspect of the invention, the brush and a distal portion of the brush drive shaft distal section are automatically extended out of the catheter lumen distal end opening when the drive member is received in and seated in the drive motor lumen upon engagement of the brush sub-assembly connector with the drive motor unit connector.

In the practice of the preferred embodiment, a guidewire is advanced to the site of a thrombus in a blood vessel lumen or the lumen of a medical implant. The proximal end of the

guidewire is inserted into the drive shaft lumen distal end opening, and the drive shaft and delivery catheter are advanced over the guidewire to the site. While the over-the-wire advancement can be performed with the brush sub-assembly coupled with the drive motor unit, doing so requires that the brush be extended from the delivery catheter lumen distal end opening. It is preferred that the brush be garaged within a distal end section of the brush delivery catheter lumen during the advancement to the site.

After the brush is advanced to the site, the proximal end of the guidewire is inserted into the drive motor unit lumen distal end opening, and the drive motor unit is advanced distally over the wire until the proximal end of the guidewire extends proximally from the drive motor unit lumen proximal end opening.

Then, the proximal drive member is axially aligned with and inserted axially into the distal drive motor lumen opening and seated therein, engaging the drive hub with the drive chuck and sealing the proximal drive motor lumen opening from the back flow of blood through the drive shaft lumen. The sub-assembly connector and the drive motor unit connector positively lock together upon axial insertion and mutual engagement of the connectors. The mutual engagement of the connectors allows rotation of the brush sub-assembly with respect to the drive motor unit to a selected angular alignment. The mutual engagement of the connectors allows the proximal drive member to be rotated by the drive motor unit at any selected angular alignment of the brush sub-assembly with respect to the drive motor unit.

In this manner, the brush is advanced out of the brush delivery catheter lumen and positioned in relation to an elongated soft obstruction. The drive shaft is rotated by energizing the drive motor in a prescribed rotation direction, and the brush is retracted proximally through the soft obstruction. A thrombolytic agent is delivered from a side port of a Y-connector and through the brush delivery catheter lumen alongside the drive shaft and out of the delivery catheter distal end opening adjacent to the brush. The fibrin of the soft obstruction is macerated by the rotating brush bristles into particles or otherwise exposed as the thrombolytic agent is delivered.

The guidewire can also be withdrawn proximally and re-inserted and advanced distally through the drive shaft lumen if necessary. The guidewire can also be inserted into and extended distally through the drive motor unit lumen from the drive motor lumen distal end opening when the brush sub-assembly is not attached. The attachment mechanism of the present invention allows this to take place without any danger that the guidewire will be damaged by effecting the attachment.

The attachment mechanism of the present invention can be effected at any angular orientation of the brush sub-assembly to the drive motor unit with or without a guidewire or microcatheter inserted through the drive shaft lumen. Then, the orientation can be adjusted by a free rotation of the drive motor unit without disturbing the attachment itself, unlike the use of a threaded or luer lock attachment mechanism. This avoids having to hold the brush sub-assembly and any guidewire or microcatheter steady while the drive motor unit is rotated to complete the attachment.

In this way, the present invention also advantageously allows the side port of the Y-connector and the tubing attached to it to be rotated to an angle that allows freedom of manipulation of the drive motor unit without tangling the tubing or imposing any load on the drive shaft and any guidewire or microcatheter inserted through the drive shaft

lumen. While the invention is preferably realized in the preferred embodiments for coupling a brush sub-assembly with a drive motor unit, it can also be employed in coupling an obstruction treatment sub-assembly with a drive motor unit.

This summary of the invention and the objects, advantages and features thereof have been presented here simply to point out some of the ways that the invention overcomes difficulties presented in the prior art and to distinguish the invention from the prior art and is not intended to operate in any manner as a limitation on the interpretation of claims that are presented initially in the patent application and that are ultimately granted.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects, advantages and features of the invention will become apparent from the following detailed description of the preferred embodiments of the invention, in which:

FIG. 1 is a plan view of a first preferred embodiment of the motor and brush assembly of the present invention;

FIG. 2 is an enlarged, plan view of the brush sub-assembly depicting the clip connector of a first embodiment of the invention;

FIG. 3 is a cross-section view of the clip connector of the first embodiment of the invention and an attached Y-connector taken along lines 3—3 of FIG. 2;

FIG. 4 is an exploded view of components of the drive motor unit of FIG. 1;

FIG. 5 is a distal end view of the drive motor unit of FIG. 1;

FIG. 6 is a proximal end view of the drive motor unit of FIG. 1;

FIG. 7 is a side partial cross-section view of the drive motor unit of FIG. 1 depicting the arrangement for receiving the brush drive shaft proximal end and for attachment with the clip connector of the brush sub-assembly;

FIG. 8 is an exploded, enlarged, perspective view of the components of the dynamic rear seal that fits in the drive motor lumen and seals the interior components of the drive motor unit from blood that backflows through the drive shaft lumen during use of the motor and brush assembly;

FIG. 9 is an end-to-end plan view of the alignment of the brush drive shaft proximal end and a guidewire proximal end prior to their insertion into the drive motor lumen distal end opening;

FIG. 10 is a side partial cross-section view of the drive motor unit depicting the insertion of the proximal end of the guidewire into the drive motor lumen distal end opening and its distal advancement through the drive motor lumen to exit its proximal end opening;

FIG. 11 depicts the partial advancement of the brush shaft proximal end into the drive motor lumen over the guidewire and the separation of the clip free ends of the clip connector as they ride upon the cam surface of the drive motor housing;

FIG. 12 is a side partial cross-section view of the drive motor unit depicting the advancement of the brush shaft proximal end into the drive motor lumen over the guidewire to the fully seated position and the engagement of the clips into the groove encircling the nose of the drive motor housing;

FIG. 13 is a distal end view of the drive motor unit and the clip connector taken along lines 13—13 of FIG. 12 and

the rotation thereof to a further angular orientation of the brush sub-assembly with the drive motor unit;

FIGS. 14 and 15 depict the insertion into the proximal end opening and distal advancement of a guidewire through the rear seal and a guide in the drive motor lumen that facilitates replacement of guidewires;

FIG. 16 is a distal end view of a further embodiment of a clip connector that is attached to the drive motor unit housing and operated to engage and disengage with the proximal end of the brush sub-assembly;

FIG. 17 is a side partial cross-section view taken along lines 17—17 of FIG. 16 of the clip connector of FIG. 16 in an open position for receiving or releasing and a closed position for engaging the proximal end of the brush sub-assembly; and

FIG. 18 is an exploded view of the components illustrated in FIG. 17 in relation with the proximal end of the brush sub-assembly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

In view of the apparent interchangeable use in the background art, only the terms “soft obstruction” or “thrombus” and “thrombectomy” will be employed in the following description of the preferred embodiments of the invention, and it will be understood that these terms shall embrace and be the equivalent of blood clot or embolus and embolectomy, respectively, and are applicable to the removal of soft, recently formed thrombi or blood clots.

FIG. 1 illustrates a motor and brush assembly 10 which incorporates one embodiment of a simplified, repeatable, precise and positive attachment mechanism of a first preferred embodiment for attaching a brush sub-assembly 100 with a drive motor unit 200. A further preferred embodiment of the attachment mechanism is depicted in FIGS. 16–18. These attachment mechanisms allow full 360° rotation of the brush sub-assembly 100 with respect to the drive motor unit 200. In addition, these attachment mechanisms precisely axially align and engage a hollow brush drive shaft of the brush sub-assembly with drive and sealing components of the drive motor unit 200 for rotation of the drive shaft and attached distal brush.

The brush sub-assembly 100, including the brush drive shaft 20, the brush delivery catheter 30, a clip connector 70 and a Y-connector 50 is also depicted separately in FIG. 2 and in FIG. 3 in part. The brush drive shaft 20 extends from its proximal end 23 to its distal end 21 through the clip connector lumen 80 of clip connector 70, the Y-connector lumen 68 of Y-connector 50 and the delivery catheter lumen 32 of delivery catheter 30. The drive shaft 20 is formed of a number of sections that are attached together in tandem and provide a continuous drive shaft lumen 28. The continuous drive shaft lumen 28 extends all the way from the drive shaft lumen proximal end opening at the proximal drive shaft end 23 to the drive shaft lumen distal end opening at distal drive shaft end 21 in which the microcatheter or guidewire 40 can be received. The drive shaft sections include a relatively long flexible, distal drive shaft section 24, a relatively short and stiff, intermediate drive shaft section 25, and a further relatively short and stiff, proximal drive shaft section 27.

The distal drive shaft section 24 is preferably formed of thin wall tube having a 1.4 mm O.D. and a 1.0 mm drive shaft lumen I.D., the thin wall tube formed of polyether amide coated over stainless steel wire braid. A distal drive

shaft portion **22** of the distal drive shaft section **24** extends outward of the distal end opening of the brush delivery catheter **30** when the brush sub-assembly **100** is attached to the drive motor unit **200** as shown in FIG. **1**. The brush **26** is formed around the periphery of the distal drive shaft portion **22** that can be retracted into the brush delivery catheter lumen **32** when the brush sub-assembly **100** is not attached to the drive motor unit **200** in a manner described below. The brush bristles may take the form of those described in the above-incorporated '653 or '355 patents or the embodiments disclosed in the above-referenced '(9135390.APP) application.

The intermediate drive shaft section **25** is preferably formed of a hypotube, e.g., a stainless steel tube, that is coated with polytetrafluoroethylene (PTFE) and has a tube O.D. and tube lumen I.D. dimensioned to receive the proximal end of the relatively flexible distal drive shaft section **24**. An enlarged, annular, distal stop **44** is formed at the junction of the proximal end of the distal drive shaft section **24** and the distal end of the intermediate drive shaft section **25** as shown in FIGS. **2** and **3**. The intermediate drive shaft section extends proximally through the Y-connector lumen **68** and then through the clip connector lumen **72** and extends proximally therefrom a further predetermined distance to its proximal end within a drive hub **90**. An enlarged, annular, proximal stop **46** is formed at a predetermined point along the length of the intermediate drive shaft section **25**.

The proximal drive shaft section **27** is also preferably formed of a hypotube, e.g., a stainless steel tube, that is coated with PTFE that has a tube O.D. and tube lumen I.D. similar to those of the distal drive shaft section **24**. The distal end of the proximal drive shaft section **27** is inserted into the tube lumen of the intermediate drive shaft section, and the drive hub **90** is formed over the junction of the proximal and intermediate drive shaft sections. The proximal drive shaft section **27** extends from that junction a predetermined distance to the proximal drive shaft end **23**.

In FIG. **2**, the proximal drive shaft section **27** and a distal portion of the intermediate drive shaft section extending to the proximal stop **46** constitute a proximal drive portion **29** of the drive shaft **20**. In FIG. **1**, the proximal drive portion **29** extends through the schematically illustrated drive motor lumen **210** of the drive motor unit **200** with the proximal drive shaft end **23** seated within seal assembly **220**. The dimensions between the proximal drive shaft end **23** and the drive hub **90** and the proximal stop **46** are selected to match the overall length of the drive motor lumen **210** drive components engaging the drive hub **90** as described below. The drive hub **90**, shown in FIG. **2**, is dimensioned and formed about the proximal drive shaft section **24** and spaced distally from proximal drive shaft end **23** sufficiently to be engaged in a drive chuck along the drive motor lumen **210** when the proximal drive shaft end **23** is seated as shown in FIG. **1**. The drive hub **90** is formed of an elongated distal cylinder **92** surrounding the drive shaft surface and an elongated proximal, square cross section bar **94** molded as a single piece over the junction of the distal and proximal ends of the proximal and intermediate drive shaft sections **27** and **25**, respectively.

The drive shaft **20** is trapped within the aligned brush delivery catheter lumen **32**, Y-connector lumen **68** and clip connector lumen **80** so that it cannot be removed therefrom. The distal and proximal stops **44** and **46**, respectively, are located a precise distance apart from one another and from the drive hub **90** and proximal drive shaft end **23** along the intermediate drive shaft section **25**. The distal stop **44** fits within the Y-connector lumen **68**, and the proximal stop **46**

is located proximal to the proximal annular seat **82** and is greater in diameter than the clip connector lumen **80**. The stops **44** and **46** allow the drive shaft **20** to be advanced distally within the aligned lumens **32**, **68** and **80** until the distal stop **46** engages against the proximal surface of the proximal annular seat **82** and advanced proximally until the distal stop **44** engages against a narrowed proximal end of the Y-connector lumen. A limited longitudinal travel sufficient to allow the brush **26** to be retracted proximally in the direction of arrows **96** and **98** of FIG. **1** and garaged within a distal section of the of the brush delivery catheter lumen **32** is thereby provided.

The brush sub-assembly **100** further includes the brush delivery catheter **30** having a catheter lumen **32** for receiving the distal drive shaft section **24** including the distal drive shaft portion upon which the brush **26** is formed. The brush delivery catheter **30** is reinforced by a reinforcing tube **34** for providing stress relief extending distally a short distance from its proximal end **36**. The reinforced proximal end **36** of the brush delivery catheter **30** is attached to the threaded distal end **60** of a Y-connector **50** through use of a threaded compression cap **48** as shown in FIG. **3**. In this way, the brush delivery catheter lumen **32** is aligned with the Y-connector lumen **68**. The brush delivery catheter **30** preferably may be about 65 cm to about 115 cm long, and have a 6 French (2.06 mm) O.D. and a lumen I.D. of about 1.73 mm. The brush delivery catheter **30** preferably is formed of a tubular wire braid that is encased in a plastic material and is relatively flexible. The brush delivery catheter distal end **38** preferably has a radiopaque ring or band formed around the distal end opening of the brush delivery catheter lumen **32**.

A side port extension **62** of Y-connector **50** provides a fluid coupling with the brush delivery catheter lumen **32** via the Y-connector lumen **68** and the side port lumen **54**. A flexible extension tube **64** extends from the side port extension **62** and terminates in an infusion port **66** for attachment to a source of thrombolytic agent (not shown).

The clip connector **70** constitutes one preferred embodiment of a brush sub-assembly connector and is coupled by a threaded distal coupling **84** to the threaded proximal end **56** of the Y-connector **50**. A clip connector barrel **71** surrounds a constant diameter clip connector lumen **80** that is thereby aligned with the Y-connector lumen **68**. An O-ring **52** is trapped in an annular recess within the lumen **68** at the threaded proximal end **56**. The O-ring lumen tightly receives and bears against the intermediate brush drive shaft section **25** extending through the lumens **68** and **80**. The clip connector lumen **80** extends to the proximal end opening thereof within an enlarged proximal annular seat **82**. The threaded female couplings **48** and **84** are tightly screwed onto the threaded male ends **60** and **56**, respectively, and adhesive may be applied to assure that the attached components cannot loosen and rotate.

The clip connector **70** further comprises a pair of moment arms **76** and **78** joined by hinges **73** and **75**, respectively, disposed at 180° apart positions on the circumference of the clip connector barrel **71** and extending proximally to either side of the proximal annular seat **82**. The free clip ends **77** and **79** of the moment arms **76** and **78**, respectively are turned inward extending radially toward one another and the axis of the connector barrel **71** to form attachment clips. The free clip ends **77** and **79** are biased by the hinges **73** and **75** to have a pre-determined separation apart from one another. The moment arms **76** and **78** also extend distally from hinges **73** and **75**, respectively, to finger grips **72** and **74**, respectively. The hinges **73** and **75** are resilient enough to allow

finger grips 72 and 74 to be squeezed together toward the barrel 71 to increase the separation of the free clip ends 77 and 79, respectively. The interaction of the free clip ends 76 and 78 with a circular retention groove 240 of drive motor unit 200 allows the attachment of the brush sub-assembly 100 with the drive motor unit 200 as described below.

A guidewire 40 is shown in FIGS. 1 and 2 extending from the distal and proximal end openings of the distal and proximal ends 21 and 23 of the drive shaft lumen 28. In FIG. 1, the guidewire 40 is depicted exiting the proximal end opening of the drive motor lumen 210. It will be understood that the guidewire 40 is provided for over-the-wire introduction and positioning of the distal end of the brush sub-assembly 100 in relation to a soft obstruction in a blood vessel or a vascular access device or the like. The guidewire 40 may be withdrawn during rotation of the brush 26, or may be left in place as described below.

Returning to the drive motor unit 200 shown in FIG. 1, it includes a battery powered drive motor, gear assembly, and a drive chuck aligned with the drive motor lumen 210 of the drive motor unit 200. The drive motor lumen 210 is schematically depicted extending in alignment with the Y-connector lumen 68 and the clip connector lumen 80. The drive motor lumen 210 terminates proximally with the proximal seal assembly 220 (shown in partial cross-section) that seals the interior of drive motor unit 200 from blood escaping from the proximal end opening of the drive shaft lumen 28.

It will be understood that drive motor unit 200 only rotates the hollow lumen drive shaft 20 and the brush 26 formed about distal drive shaft section 22. The internal drive motor is turned on by depression of push-button switch 230 which closes and provides battery power to the internal drive motor. In a thrombectomy application, the internal drive motor rotates the drive shaft 20 relatively slowly, on the order of about 500–3000 RPM and in a single direction.

As noted above, a thrombolytic agent is delivered into the space in Y-connector lumen 68 outside of the outer surface of the proximal drive shaft section 24 shown in FIG. 3. The trapped O-ring 52 within compression cap 84 provides a rotary seal within the proximal end of the Y-connector 50 for sealing around the exterior surface of the proximal drive shaft section 24. The compressed O-ring 52 inhibits the back flow of thrombolytic agent or blood through the clip connector lumen 80 and into the drive motor lumen 210. The thrombolytic agent is forced distally through the annular space between the outer surface of the proximal drive shaft section 24 and the inner surface of the brush delivery catheter 30 until it escapes from the annular opening at the brush delivery catheter distal end 38.

The rotation of the brush 26 to separate and mix the fibrin of a soft obstruction while a thrombolytic agent is supplied to it generally follows the teachings of the above-incorporated '653 patent. The attachment mechanisms, the proximal seal assembly 220, and other features of the drive motor unit 200 of the present invention are not disclosed in the above-incorporated '653 and '355 patents or employed in the earlier above-referenced Cragg Thrombolytic Brush™ system.

FIGS. 4–8 depict the components and construction of the drive motor unit 200 in greater detail. The drive motor unit 200 is formed with a proximal housing section 202 and a distal housing section 204 that are molded of plastic material and adhered together at an overlapping seam 206. The proximal housing section 202 is formed with a receptacle 208 and pin 212 for receiving an integral battery and DC

drive motor 214. The battery and drive motor 214 are coupled electrically to a switch button 230 in housing half section 204 which applies battery power to the drive motor to rotate the drive shaft 262 and the drive gear 264 attached to it.

The teeth of the drive gear 264 mesh with teeth of a driven gear 274 which is formed integrally with a chuck body 270 for receiving the drive shaft hub 90. The integral chuck and driven gear unit 290 is supported to be in axial alignment with and define part of the drive motor lumen 210. The drive motor lumen 210 extends between the proximal lumen end opening 248 and the distal lumen end opening 246. First and second proximal lumen cylindrical bores 250 and 252 extend distally from the proximal drive motor lumen end opening 248 to a conical guide 252 that surrounds a bore 256 through the end of the first cylindrical bore 250. The second cylindrical bore 252 houses the components of the dynamic seal 220.

The dynamic seal 220 is also shown in the end view of FIG. 6 and the perspective view of FIG. 8. The dynamic seal and is formed of a rigid plastic proximal cylindrical guide member 222, a rigid plastic distal cylindrical guide member 226 and a soft silicone rubber annular O-ring 224. The proximal guide member 222 has an axial bore 236 extending through it from a conical or funnel shaped, proximal guide 228 formed in its proximal surface to an annular seat 234 formed in its distal surface. The distal guide member 226 has a funnel or conical shaped, distal guide 232 formed in its distal surface. The O-ring 224 is trapped between members 222 and 226 in the seat 224 and it forms a sealing orifice that bears against the outer surface of drive shaft proximal section 24 when it is inserted through it and its proximal end 23 seated proximally to the location of the O-ring 224. The dynamic seal 220 is axially inserted into the second bore 252 until it abuts the distal end thereof and is sealed in place.

The integral chuck and driven gear unit 290 is supported to be in alignment with and define part of the drive motor lumen 210 by cooperation with a distal support tube 205 (shown in FIG. 7) and a proximal support tube 260. The distal support tube 205 is formed integrally with the distal housing section 204 and extends proximally therein and in axial alignment with the drive motor lumen 210 and distal drive motor lumen end opening 246. The free end 207 of the distal support tube 205 provides a bearing surface for engagement against an annular distal shoulder 271 of the integral chuck and driven gear unit 290. A distal end of the proximal support tube 260 is pressed into the bore 278 of the proximal axis extension 276 of the integral chuck and driven gear unit 290. The proximal end of the support tube 260 bears against an annular seat 258 surrounding the bore 256. The lumen diameter of the support tube 260 is sized to allow passage of the brush drive shaft proximal section 24 there-through. When the components of FIG. 4 are fitted together in the manner shown in FIG. 7, the drive motor lumen 210 is formed, and the teeth of the drive gear 264 mesh with the teeth of the driven gear 274.

The integral chuck and driven gear unit 290 also comprises the expandable drive chuck 280 which is formed of four 90° section chuck elements that together encircle a circular bore 288. Two of the chuck elements 282 and 284 are depicted in the cross-section view. The four chuck elements are attached at their proximal ends to the chuck body 270 and extend distally to free ends that are tapered to form a conical distal entrance into the circular chuck bore 288. The proximal end of the circular bore 288 is aligned with the square chuck bore 286. The circular and square chuck bores are dimensioned to receive the cylinder 92 and

bar 94, respectively, of the drive hub 90. The four chuck elements spread apart at their free ends within the bore of tube 205 as the hemispheric ends of the cylinder 92 are pushed against them proximally during insertion and or pulled against them distally during retraction as shown in FIG. 11.

In the first preferred embodiment of the drive motor unit connector 239, the drive motor unit housing 204 is formed with an annular, dome shaped cam surface 242 surrounding the drive motor unit distal end opening 246 as shown also in FIG. 5. The cam surface 242 increases in diameter radially outward from the axis of the drive motor unit lumen 210. The cam surface 242 is maximally bounded by an annular retention groove 240 recessed into the drive motor unit housing. An annular, proximally extending, drive motor unit receptacle 244 is formed within the dome shaped projection that also surrounds the drive motor unit distal end opening 246. The annular retention groove 240 surrounding the annular receptacle 244, the annular receptacle 244, and the cam surface 242 extending therebetween comprise the drive motor unit connector 239.

FIG. 9 is an end-to-end plan view of the alignment of the brush proximal drive shaft end 23 and a guidewire proximal end 41 prior to their insertion into the distal drive motor lumen end opening 246. FIG. 9 also depicts the dimensional relation between the components of the proximal drive portion 29 and the mating components of the sub-assembly connector 70 and along the drive motor lumen 210. The proximal drive portion 29 is defined by the portion of the proximal drive shaft section 24 that is proximal to and includes the proximal stop 46. All of the proximal drive portion 29 is adapted to be received within the drive motor unit lumen 210.

In FIG. 9, the distal stop 44 is depicted withdrawn proximally against the proximal annular seat 82 in contrast to the position depicted in FIG. 2. This withdrawal is effected manually. The brush 26 and distal drive shaft section 22 are retracted into the brush delivery catheter lumen 32 to facilitate advancement of the brush sub-assembly 100 over the guidewire 40 to the site of the soft obstruction. The brush bristles of brush 26 are preferably formed as described in the above-referenced '9135390.APP) application. The brush bristles are folded down "with the grain" against the distal drive shaft section 22 and the surrounding inner wall of catheter lumen 32 and extend distally as they are garaged therein.

FIG. 10 is a side partial cross-section view of the drive motor unit 200 depicting the insertion of the guidewire proximal end 41 into the distal drive motor lumen end opening 246 and its distal advancement through the drive motor lumen 210 to exit its proximal end opening 248. The conical guide surfaces of the expandable chuck 280 and the guide funnel 232 direct and guide the proximal advancement of the guidewire proximal end 41 through the drive motor lumen 210. The brush sub-assembly 100 and the drive motor unit 200 are then positioned to be brought together by attachment of the sub-assembly connector 70 with the drive motor unit connector 239.

FIG. 11 depicts the partial proximal advancement of the brush shaft proximal drive portion 29 into the drive motor lumen 210 over the guidewire 40. The clip ends 77 and 79 of the clips 76 and 78 ride upon and are separated apart by the cam surface 242. The proximal drive shaft end 23 approach the O-ring seal 224. The four chuck elements of drive chuck 280 are spread apart at their free ends within the bore of tube 205 by the outer surface of the cylinder 92. The bar 94 is already inserted partly into the square chuck bore 286.

FIG. 12 is a side partial cross-section view of the drive motor unit 200 depicting the full advancement of the proximal drive portion 29 into the drive motor lumen 210 over the guidewire 40 to the fully seated position. The clip ends 77 and 79 are dropped into the retention groove 240. FIG. 13 is a distal end view of the drive motor unit 200 and the clip connector 70 taken along lines 13—13 of FIG. 12. FIG. 13 depicts the rotation of the clip connector 70 to a further angular orientation of the brush sub-assembly 100 with respect to the drive motor unit 200.

The attachment of the brush sub-assembly connector 70 with the drive motor unit connector 239 is thus effected by axially aligning the proximal seat 82 with the annular receptacle 244 and pressing the free clip ends 77 and 79 against the cam surface 242 to cause the free clip ends 77 and 79 to ride upon the cam surface 242 and to separate apart. The separation continues until the free clip ends 77 and 79 slip into the retention groove 240 and lock therein. The clip connector 70, the Y-connector 50 and the drug delivery catheter 30 can be rotated manually through 360° around the brush drive shaft 20 and the guidewire 40 as the free clip ends 77 and 79 slip along and within the retention groove 240.

The detachment of the free clip ends 77 and 79 from the retention groove 240 for removing the brush sub-assembly 100 from the drive motor unit 200 is effected by depressing the finger grips 72 and 74 toward one another and drawing the drive motor unit 200 and brush sub-assembly apart. The hinges 73 and 75 (FIG. 3) allow the finger grips 72 and 74 to be squeezed together toward the connector barrel 71 which increases the separation of the free clip ends 77 and 79 until they are released from the retention groove 240.

Summarizing the use of the motor and brush assembly 10 in a thrombolytic procedure, a percutaneous access is provided into an occluded medical implant lumen or into vasculature leading to an occluded native blood vessel or vascular implant in a conventional manner as disclosed in the above-incorporated '653 patent and Cragg Thrombolytic Brush™ literature, for example. The guidewire 40 is advanced through the access device and the vasculature or directly into the accessed medical implant until its distal end passes through the soft obstruction in the lumen thereof. The guidewire proximal end 41 extends proximally from the vasculature access device extending through the skin. Then, it is possible to advance the brush sub-assembly 100 over the guidewire 40 while the distal brush 26 is garaged within the distal section of the brush delivery catheter lumen 32 as described above with respect to FIG. 9. The advancement of the distal ends of the brush delivery catheter 30 and the drive shaft 20 can be monitored by observing the distal end radiopaque markers using fluoroscopy. When the site of the soft obstruction is reached, advancement over the guidewire 40 is halted. Typically, the brush sub-assembly is advanced over the guidewire until it is disposed distally of the soft obstruction so that it can be treated as described below in sections as the brush sub-assembly is retracted proximally through it.

After the soft obstruction is reached, the guidewire proximal end 41 is inserted into the distal drive motor lumen end opening 246 as described with reference to FIGS. 9 and 10 until the guidewire distal end 43 of the guidewire 40 extends proximally from the proximal seal assembly 220. At this point, the proximal drive shaft end 23 is inserted into the distal drive motor lumen end opening 246 and advanced as described with reference to FIGS. 11 and 12. During the approach, the clips 76 and 78 spread apart as the respective clip free ends 77 and 79 bear against and then ride up on the

generally conical cam surface **242**. When the clip free ends **77** and **79** snap into the annular retention groove **240**, a number of operations are completed and connections are made. Simultaneously, the proximal drive shaft end **23** is seated into the proximal seal assembly **220**, the enlarged shaft hub **90** is seated into the drive chuck receptacles **286** and **288**, the brush **26** is advanced distally out of the distal section of the brush delivery catheter lumen **32**, and the proximal stop **46** fits into the distal drive motor lumen end opening **246**.

When assembly is complete as shown in FIG. 1, the brush sub-assembly **100** and the drive motor unit **200** can be rotated with respect to one another to orientations that facilitate the infusion and manual manipulation of the assembly by the physician as shown in FIG. 13. Then, the drive motor unit switch **230** is closed to energize the drive motor. The brush **26** is rotated through rotation of the drive shaft **20** by the proximal drive motor unit **200** in the prescribed rotation direction for macerating the soft obstruction. At the same time, a thrombolytic agent is applied through the side extension **62** and through the brush delivery catheter lumen **32** to the region of the brush **26**. The rotation of the brush bristles causes the brush **26** to macerate the soft obstruction and to impart a rotational velocity to the fragments. In such clinical use, the brush **26** is rotated at a speed and direction that effects a pumping action in the blood that maintains the soft obstruction fragments in contact with the delivered thrombolytic agent rather than moving the mixture distally away from the brush **26**.

The guidewire **40** can be left in place during rotation of the brush **26** or it can be retracted from the drive shaft lumen **28** and the proximal drive motor lumen end opening **248**. The guidewire or a different guidewire, infusion wire, or a balloon or basket bearing guidewire or miniature catheter can be advanced distally into the exposed drive shaft lumen proximal end opening and out of the distal end opening thereof.

When the guidewire **40** or other elongated medical device is inserted through the drive shaft lumen **28**, some amount of blood and infused thrombolytic agent leaks back through it and escapes from the drive shaft lumen proximal end opening. The blood escapes proximally to the dynamic seal assembly **220**, and the dynamic seal assembly **220** prevents it from infiltrating into the interior of the drive motor unit **200**. Appreciably greater amounts of blood and infused thrombolytic agent are emitted from the drive shaft lumen proximal end opening when the guidewire **40** is removed from the drive shaft lumen **28**. In this case, the physician can stop the proximal drive motor lumen end opening **248** with a finger. Again, the blood pools in the opening proximally to the dynamic seal assembly **220**, and the dynamic seal assembly **220** prevents it from infiltrating into the interior of the drive motor unit **200**.

At times, it is also desirable to be able to advance a guidewire **40** or other elongated medical device distally through the drive motor lumen **210** when the proximal drive portion **29** is not seated therein. FIGS. 14 and 15 depict the insertion of the guidewire distal end **43** into the proximal drive motor lumen end opening **248** and distal advancement of a guidewire **40** through the dynamic rear seal **220** and through distal conical guide **254** that facilitates such distal advancement of a guidewire **40**.

When assembly is complete as shown in FIG. 1, the brush sub-assembly **100** and the drive motor unit **200** can be rotated with respect to one another to orientations that facilitate the infusion and manual manipulation of the

assembly by the physician as shown in FIG. 13. Then, the drive motor unit switch **230** is closed to energize the drive motor. The brush **26** is rotated through rotation of the drive shaft **20** by the proximal drive motor unit **200** in the prescribed rotation direction for macerating the soft obstruction. At the same time, a thrombolytic agent is applied through the side extension **62** and through the brush delivery catheter lumen **32** to the region of the brush **26**. The rotation of the brush bristles causes the brush **26** to macerate the soft obstruction and to impart a rotational velocity to the fragments. In such clinical use, the brush **26** is rotated at a speed and direction that effects a pumping action in the blood that maintains the soft obstruction fragments in contact with the delivered thrombolytic agent rather than moving the mixture distally away from the brush **26**.

The guidewire **40** can be left in place during rotation of the brush **26** or it can be retracted from the drive shaft lumen **28** and the drive motor lumen proximal end opening **248**. The guidewire or a different guidewire, infusion wire, or a balloon or basket bearing guidewire or miniature catheter can be advanced distally into the exposed proximal drive shaft lumen end opening and out of the distal end opening thereof.

When the guidewire **40** or other such device is inserted through the drive shaft lumen **28**, some amount of blood and infused thrombolytic agent leaks back through it and escapes from the drive shaft lumen proximal end opening. The blood escapes proximally to the dynamic seal assembly **220**, and the dynamic seal assembly **220** prevents it from infiltrating into the interior of the drive motor unit **200**. Appreciably greater amounts of blood and infused thrombolytic agent are emitted from the drive shaft lumen proximal end opening when the guidewire **40** is removed from the drive shaft lumen **28**. In this case, the physician can stop the proximal drive motor lumen opening **248** with a finger. Again, the blood pools in the opening proximally to the dynamic seal assembly **220**, and the dynamic seal assembly **220** prevents it from infiltrating into the interior of the drive motor unit **200**.

At times, it is also desirable to be able to advance a guidewire **40** distally through the drive motor lumen **210** when the proximal drive portion **91** is not seated therein. For example, during a medical thrombectomy procedure, a guidewire may be damaged and have to be replaced while the brush is kept housed within the brush delivery catheter lumen. The brush sub-assembly **100** can be disconnected from the drive motor unit **200** and the guidewire distal end **43** advanced through the drive shaft lumen **32**, and the guidewire proximal end **41** can be inserted into and advanced proximally through the drive motor lumen **210**. Alternatively, the guidewire distal end **43** can be advanced first through the drive motor lumen **210** and then through the drive shaft lumen **32**. In either case, the brush sub-assembly **100** and the drive motor unit **200** can then be reattached after replacement and repositioning of the guidewire **40** to expel the brush from the brush delivery catheter lumen. FIGS. 14 and 15 depict the insertion into the drive motor lumen proximal end opening **248** and distal advancement of a guidewire **40** through the dynamic rear seal **220** and through distal conical guide **254** that facilitates such distal advancement of a guidewire **40**.

A second embodiment of the mating connector assembly for allowing 360° rotation of the brush sub-assembly with respect to the drive motor unit is depicted in FIGS. 16–18. In this embodiment, a clip connector **170** is attached to the drive motor unit housing **204** and is operated to engage and disengage with the annular distal attachment rim **182** of the

proximal seat **82** of the brush sub-assembly **100**. The brush sub-assembly **100** is only otherwise modified from that shown in FIGS. 1-15 by removal of the brush sub-assembly connector **70**. No retention groove is employed in housing section **204**.

The clip connector **170** further comprises a pair of moment arms **176** and **178** joined by hinges **173** and **175**, respectively, to a circular clip connector ring **190** as a unitary structure. The moment arms are disposed at 180° apart positions on the circumference of the clip connector barrel **171** and extend proximally alongside and outwardly of the housing section **204**. The free clip ends **177** and **179** of the moment arms **176** and **178**, respectively are arcuate in shape. The free clip ends **177** and **179** extend inward toward the axis of distal drive motor lumen end opening **246** sufficiently to rest against arcuate sections of the attachment rim **182**. The arcuate free clip ends **177** and **179** are biased by the hinges **173** and **175** to have a predetermined separation apart from one another which corresponds to the outer diameter of sub-assembly connector barrel **171**. The moment arms **176** and **178** also extend proximally from hinges **173** and **175**, respectively, to finger grips **172** and **174**, respectively. The hinges **173** and **175** are resilient enough to allow finger grips **172** and **174** to be squeezed together toward the housing section **204** to increase the separation of the arcuate free clip ends **177** and **179**, respectively, as shown in the broken line position of FIG. 17.

The connector ring **190** is fitted into and adhered around its outer wall to the annular receptacle **244**. A resilient O-ring **180** is fitted into the annular receptacle **244** against the inner wall of connector ring **190** and retained there by inwardly extending arcuate clips **192** and **194**. The distance between the arcuate clips is greater than the outer diameter of the seat **82**.

The attachment of the brush sub-assembly connector **182** with the drive motor unit connector **170** is effected by axially aligning the proximal face of seat **82** with the O-ring **180** in annular receptacle **244** and pressing it against the arcuate free clip ends **177** and **179**. The slight radius of the proximal face of seat **82** causes the free clip ends **177** and **179** to separate apart. The separation continues until the free clip ends **177** and **179** slip over the seat **82** and against the distal rim **182** and lock against it. The seat **82**, the Y-connector **50** and the drug delivery catheter **30** can be rotated manually through 360° around the brush drive shaft **20** and the guidewire **40** as the free clip ends **177** and **179** slip along and around the distal rim **182**.

The detachment of the free clip ends **177** and **179** from engagement against the distal rim **182** for removing the brush sub-assembly **100** from the drive motor unit **200** is effected by depressing the finger grips **172** and **174** toward one another and drawing the drive motor unit **200** and brush sub-assembly apart. The hinges **173** and **175** allow the finger grips **172** and **174** to be squeezed together toward the drive motor housing section which increases the separation of the free clip ends **177** and **179** until the distal rim **182** can be released.

In any of the embodiments described above, the apparatus may be modified to allow infusate to be delivered down the drive shaft lumen **26** as disclosed in certain embodiments of the above-incorporated '653 patent. The distal drive shaft section **22** may be pre-formed with weep holes or perforations to allow the dispersion of dissolving agents or other fluids introduced down the lumen while the guidewire **40** is present or after it is withdrawn. The drive shaft lumen distal end opening may be provided with self sealing flaps to seal

about the guidewire **40** while the brush is advanced or to seal the lumen end opening after the guidewire **40** is retracted. This ensures that the introduced fluid is dispersed within or proximal to the brush bristles. The drive shaft lumen distal end opening may alternatively be left open to provide a fluid dispersion or flush operation distal to the brush **26**. These and other features of and methods of use of the brush described in the above-incorporated '653 and '355 patents may be employed in the use of the miniaturized brush of the present invention.

The miniaturized brush of the present invention provide reduced overall outer diameter that enables its introduction through small diameter brush delivery catheter and/or blood vessel lumens. In addition, the thin wall construction provides a drive shaft lumen **28** with a relatively enlarged inner diameter for introduction over a guidewire that may be 0.035 inches in diameter, for example, and for introduction and passage of fluids therethrough. The drive shaft **20** in each assembly is reinforced sufficiently to allow advancement through tortuous blood vessel passageways and to provide torque transfer to the distal brush **10**, **10'**.

In the preferred embodiment of the invention, no further apparatus is employed or steps taken to dissolve the soft obstruction or thrombus in situ. It is expected that the treatment will be commenced within hours of the onset of diagnosis, and the thrombus will be dissolved by the brushing action continually exposing the fibrin of the obstruction to the dissolving agent. To the extent that fragments are created, the agent should dissolve them before they are swept away by blood flow.

In order to contain released fragments so that the dissolving agent may complete dissolution, the brush may be introduced through the soft obstruction downstream and rotated as the brush is slowly retracted through the obstruction. Optionally, a balloon catheter or a mesh basket may be coaxially introduced through the drive shaft lumen and placed downstream to temporarily obstruct the blood and dissolving agent flow away from the site and restrain fragments to allow the concentrated dissolving agent to complete the dissolution thereof.

Advantageously, blood clots and thrombi are more readily dissolved by the mixing action of the brush bristles as the dissolving agent is introduced. Intimal hyperplasia and the risk of vessel wall rupture or pseudoneurism is decreased by use of the soft brush bristles. The speed of dissolution may be reduced to minutes, in comparison with hours for introduction of the dissolving agent alone. The reduced amount of dissolving agent introduced decreases the risk of internal bleeding. Patient comfort is increased and cost of the intensive care treatment is reduced by the shortened time and reduction of exposure to the dissolving agent.

While the invention is preferably used in the above-described medical procedures, it will be recognized that a miniaturized, hollow lumen brush may have other important medical applications. For example, the disclosed assembly may be employed for specimen collection from various body lumens including blood vessels and other vessels, openings, cavities or ducts, in the manner of a cytology brush.

Moreover, while the present invention is described as particularly usable and implemented in the above described thrombolytic brush embodiments, it will be recognized that it can also be employed in other motor driven catheter applications employing other rotated obstruction treatment devices. For example, the obstruction treatment device of the following claims preferably constitutes the above-described flexible brush for macerating soft obstructions.

However, the obstruction treatment device can take other forms proposed for removing such soft obstructions or hard obstructions of a body vessel or vascular implant or other lumen that are rotated by a drive motor unit. Such obstruction treatment devices include expandable in situ or fixed diameter wire coils or baskets of the types shown, for example, in U.S. Pat. Nos. 4,646,736, 5,195,954 and 5,330,484, incorporated herein by reference. The obstruction treatment device can also take the form of a cutting mechanism, e.g., an atherectomy cutting head of one of the many known types, e.g. the cutting screw shown in U.S. Pat. No. 5,423,799 or the expandable wires or blades shown in U.S. Pat. No. 5,030,201, both incorporated herein by reference.

Although the preferred embodiments of the invention described above are used with hollow drive shaft **20**, it will be understood that the same connector techniques can be used to connect brush and obstruction treatment device sub-assemblies having solid core, rotatable drive shafts with drive motor units.

Although particular embodiments of the invention have been described herein in some detail, this has been done for the purpose of providing a written description of the invention in an enabling manner and to form a basis for establishing equivalents to structure and method steps not specifically described or listed. It is contemplated by the inventors that the scope of the limitations of the following claims encompasses the described embodiments and equivalents thereto now known and coming into existence during the term of the patent. Thus, it is expected that various changes, alterations, or modifications may be made to the invention as described herein without departing from the spirit and scope of the invention as defined by the appended claims.

We claim:

1. A motor and brush assembly preferably for use in a medical procedure at a site within a patient's body comprising:

a brush sub-assembly comprising:

an elongated, flexible, rotatable brush drive shaft extending between a proximal drive shaft end and a distal drive shaft end;

a brush formed in a distal portion of the brush drive shaft;

a proximal drive member formed in a proximal portion of said brush drive shaft;

an elongated, flexible, brush delivery catheter extending between a proximal catheter end and a distal catheter end and formed with a catheter lumen extending between proximal and distal catheter lumen end openings at the proximal and distal catheter ends;

fitting means for fitting a distal drive shaft section of said brush drive shaft within said catheter lumen and for extending said proximal drive member proximally of said proximal catheter lumen end opening for allowing rotation of said brush drive shaft with respect to said brush delivery catheter; and

a brush sub-assembly connector having a proximal seat extending proximally from said fitting means through which said proximal drive member extends proximally; and

a drive motor unit adapted to be coupled with said brush sub-assembly to effect rotation of said brush drive shaft further comprising:

a drive motor housing containing a drive motor lumen extending between drive motor lumen proximal and distal end openings in said drive motor housing, said

drive motor lumen dimensioned to receive said proximal drive member;

drive means located within said drive motor housing for engaging said proximal drive member when it is inserted through said distal drive motor lumen end opening and into said drive motor lumen and for rotating said drive shaft; and

a drive motor unit connector having a drive motor unit receptacle for engaging said brush sub-assembly proximal seat as said proximal drive member is advanced proximally through said distal drive motor lumen end opening and into said drive motor lumen to seat said proximal drive member in said drive motor lumen and retain said proximal drive member in engagement with said drive means located within said drive motor housing, said drive motor unit connector and said brush sub-assembly connector cooperatively allowing slidable rotation of said proximal seat with respect to said drive motor unit receptacle to a selected angular alignment of said brush sub-assembly to said drive motor unit while maintaining said proximal drive member seated in said drive motor lumen and in engagement with said drive means.

2. The assembly of claim **1**, wherein:

said fitting means of said brush sub-assembly further comprises an adaptor having an adaptor body axially aligned with said brush delivery catheter and enclosing an adaptor lumen aligned axially with said catheter lumen and coupled with said proximal catheter lumen end opening having and a side port extending laterally to the adaptor body and the axial direction of said brush drive shaft having a side port lumen for coupling with a source of diagnostic or therapeutic agent for introduction of such diagnostic or therapeutic agent into said brush delivery catheter lumen for transmission through said catheter lumen alongside said distal drive shaft section within said catheter lumen and emission from said catheter lumen distal end opening; and

said drive motor unit connector and said brush sub-assembly allow rotation of said brush sub-assembly with respect to said drive motor unit to any selected angular alignment to accommodate the direction that the side port extends when coupled with the source of diagnostic or therapeutic agent.

3. The assembly of claim **2**, wherein:

said drive means further comprises a drive motor and power supply coupled to said drive motor through a switch that is manually engageable while said drive motor housing is manipulated to rotate said brush drive shaft; and

said drive motor unit connector and said brush sub-assembly allow rotation of said brush sub-assembly with respect to said drive motor unit to any selected angular alignment to accommodate the direction that the side port extends when coupled with the source of diagnostic or therapeutic agent and to enable the manipulation of the motor drive housing and operation of the switch.

4. The assembly of claim **3**, wherein:

said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor unit receptacle to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and

said brush sub-assembly connector comprises a clip connector further comprising:

a clip connector barrel enclosing a clip connector lumen that is axially aligned to the adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said brush sub-assembly connector with said drive motor unit connector; and

a moment arm joined by a resilient hinge to the clip connector barrel extending outward of the clip connector barrel, the moment arm extending proximally from said resilient hinge alongside said proximal drive member to a free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat,

whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive member through said drive motor lumen brings said free clip end into contact with said camming surface to bias said free clip end radially away from said proximal drive member against said resilient hinge until said free clip end engages said annular retention groove and said proximal seat is seated within said drive motor lumen distal end opening, whereupon said brush sub-assembly and said drive motor unit can be rotated with respect to one another as said free clip end traverses and is retained in said annular retention groove.

5. The assembly of claim 4, wherein said clip connector further comprises:

a finger grip formed in a distal extension of said moment arm extending distally from said resilient hinge alongside said barrel, whereby said free clip end can be retracted away and released from said retention groove by depression of said finger grip toward said barrel in order to retract said proximal drive member from said drive motor lumen.

6. The assembly of claim 3, wherein:

said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor lumen distal end opening to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and

said brush sub-assembly connector comprises a clip connector further comprising:

a clip connector barrel enclosing a clip connector lumen that is axially aligned to the adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said brush sub-assembly connector with said drive motor unit connector; and

a first moment arm joined by a first resilient hinge to the clip connector barrel at a first hinge location extend-

ing outward of the clip connector barrel, the first moment arm extending proximally from said first resilient hinge alongside said proximal drive member to a first free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat; and

a second moment arm joined by a second resilient hinge to the clip connector barrel at a second hinge location extending outward of the clip connector barrel disposed at 180° to said first hinge location, the second moment arm extending proximally from said second resilient hinge alongside said proximal drive member to a second free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat,

whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive member through said drive motor lumen brings said first and second free clip ends into contact with said camming surface to bias said first and second free clip ends radially away from said proximal drive member against said first resilient hinge until said first and second free clip ends engage said annular retention groove and said proximal seat is seated within said drive motor receptacle surrounding said drive motor lumen distal end opening, whereupon said brush sub-assembly and said drive motor unit can be rotated with respect to one another through as said first and second free clip ends traverse and are retained in said annular retention groove.

7. The assembly of claim 6, wherein said clip connector further comprises:

a first finger grip formed in a distal extension of said first moment arm extending distally from said first resilient hinge along one side of said barrel; and

a second finger grip formed in a distal extension of said second moment arm extending distally from said second resilient hinge along an opposite side of said barrel, whereby said first and second free clip ends can be retracted away and released from said retention groove by depression of said first and second finger grips toward said barrel in order to retract said proximal drive member from said drive motor lumen.

8. The assembly of claim 1, wherein:

said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor lumen distal end opening to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and

said brush sub-assembly connector comprises a clip connector further comprising:

a clip connector barrel enclosing a clip connector lumen that is axially aligned to the adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said

brush sub-assembly connector with said drive motor unit connector; and

a moment arm joined by a resilient hinge to the clip connector barrel extending outward of the clip connector barrel, the moment arm extending proximally from said resilient hinge alongside said proximal drive member to a free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat, whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive member through said drive motor lumen brings said free clip end into contact with said camming surface to bias said free clip end radially away from said proximal drive member against said resilient hinge until said free clip end engages said annular retention groove and said proximal seat is seated against said drive motor unit receptacle surrounding said drive motor lumen distal end opening, whereupon said brush sub-assembly and said drive motor unit can be rotated with respect to one another as said free clip end traverses and is retained in said annular retention groove.

9. The assembly of claim 8, wherein said clip connector further comprises:

a finger grip formed in a distal extension of said moment arm extending distally from said resilient hinge alongside said barrel, whereby said free clip end can be retracted away and released from said retention groove by depression of said finger grip toward said barrel in order to retract said proximal drive member from said drive motor lumen.

10. The assembly of claim 1, wherein:

said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor lumen distal end opening to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and

said brush sub-assembly connector comprises a clip connector further comprising:

a clip connector barrel enclosing a clip connector lumen that is axially aligned to the adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said brush sub-assembly connector with said drive motor unit connector; and

a first moment arm joined by a first resilient hinge to the clip connector barrel at a first hinge location extending outward of the clip connector barrel, the first moment arm extending proximally from said first resilient hinge alongside said proximal drive member to a first free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat; and

a second moment arm joined by a second resilient hinge to the clip connector barrel at a second hinge

location extending outward of the clip connector barrel disposed at 180° to said first hinge location, the second moment arm extending proximally from said second resilient hinge alongside said proximal drive member to a second free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat, whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive member through said drive motor lumen brings said first and second free clip ends into contact with said camming surface to bias said first and second free clip ends radially away from said proximal drive member against said first resilient hinge until said first and second free clip ends engage said annular retention groove and said proximal seat is seated within said drive motor unit receptacle surrounding said drive motor lumen distal end opening, whereupon said brush sub-assembly and said drive motor unit can be rotated with respect to one another as said first and second free clip ends traverse and are retained in said annular retention groove.

11. The assembly of claim 10, wherein said clip connector further comprises:

a first finger grip formed in a distal extension of said first moment arm extending distally from said first resilient hinge along one side of said barrel; and

a second finger grip formed in a distal extension of said second moment arm extending distally from said second resilient hinge along an opposite side of said barrel, whereby said first and second free clip ends can be retracted away and released from said retention groove by depression of said first and second finger grips toward said barrel in order to retract said proximal drive member from said drive motor lumen.

12. The assembly of claim 1, wherein:

said drive motor unit connector comprises first and second moment arms that are hinged with respect to said drive motor unit receptacle, said first and second moment arms extending proximally from first and second hinges to first and second finger grips, respectively, and extending to first and second arcuate clips that extend inward into the annular drive motor unit receptacle in the unstressed position of the moment arms;

said brush sub-assembly connector comprises a barrel surrounding a barrel lumen terminating in an enlarged annular proximal seat formed with a distal rim adapted to be engaged by said first and second arcuate clips when said proximal seat is received within said annular receptacle,

whereby said first and second finger grips are adapted to be depressed inward toward the drive motor unit housing to move the arcuate clips outward so that the annular proximal seat can be inserted into the annular proximally extending receptacle and said first and second arcuate clips engage the distal rim on release of the tension applied to said first and second finger grips.

13. The assembly of claim 12, wherein said drive motor unit connector further comprises a resilient O-ring inserted within the annular proximally extending receptacle to provide a resilient seating engagement with the annular proximal seat of the barrel so that the arcuate clips force the annular proximal seat against the O-ring to compress it slightly, and the compressed O-ring tensions the attachment between the arcuate clips and the distal rim.

14. A motor and obstruction treatment device assembly preferably for use in a medical procedure at a site within a patient's body comprising:
- an obstruction treatment device sub-assembly comprising:
 - an elongated, flexible, rotatable obstruction treatment device drive shaft extending between a proximal drive shaft end and a distal drive shaft end;
 - an obstruction treatment device formed in a distal portion of the obstruction treatment device drive shaft;
 - a proximal drive member formed in a proximal portion of said obstruction treatment device drive shaft;
 - an elongated, flexible, obstruction treatment device delivery catheter extending between a proximal catheter end and a distal catheter end and formed with a catheter lumen extending between proximal and distal catheter lumen end openings at the proximal and distal catheter ends;
 - fitting means for fitting a distal drive shaft section of said obstruction treatment device drive shaft within said catheter lumen and for extending said proximal drive member proximally of said proximal catheter lumen end opening for allowing rotation of said obstruction treatment device drive shaft with respect to said obstruction treatment device delivery catheter; and
 - an obstruction treatment device sub-assembly connector having a proximal seat extending proximally from said fitting means through which said proximal drive member extends proximally; and
 - a drive motor unit adapted to be coupled with said obstruction treatment device sub-assembly to effect rotation of said obstruction treatment device drive shaft further comprising:
 - a drive motor housing containing a drive motor lumen extending between drive motor lumen proximal and distal end openings in said drive motor housing, said drive motor lumen dimensioned to receive said proximal drive member;
 - drive means located within said drive motor housing for engaging said proximal drive member when it is inserted through said distal drive motor lumen end opening and into said drive motor lumen and for rotating said drive shaft; and
 - a drive motor unit connector having a drive motor unit receptacle for engaging said obstruction treatment device sub-assembly proximal seat as said proximal drive member is advanced proximally through said distal drive motor lumen end opening and into said drive motor lumen to seat said proximal drive member in said drive motor lumen and retain said proximal drive member in engagement with said drive means located within said drive motor housing, said drive motor unit connector and said obstruction treatment device sub-assembly connector cooperatively allowing slidable rotation of said proximal seat with respect to said drive motor unit receptacle to a selected angular alignment of said obstruction treatment device sub-assembly to said drive motor unit while maintaining said proximal drive member seated in said drive motor lumen and in engagement with said drive means.
15. The assembly of claim 14, wherein:
- said fitting means of said obstruction treatment device sub-assembly further comprises an adaptor having an adaptor body axially aligned with said obstruction

- treatment device delivery catheter and enclosing an adaptor lumen aligned axially with said catheter lumen and coupled with said proximal catheter lumen end opening having and a side port extending laterally to the adaptor body and the axial direction of said obstruction treatment device drive shaft having a side port lumen for coupling with a source of diagnostic or therapeutic agent for introduction of such diagnostic or therapeutic agent into said obstruction treatment device delivery catheter lumen for transmission through said catheter lumen alongside said distal drive shaft section within said catheter lumen and emission from said catheter lumen distal end opening; and
 - said drive motor unit connector and said obstruction treatment device sub-assembly allow rotation of said obstruction treatment device sub-assembly with respect to said drive motor unit to any selected angular alignment to accommodate the direction that the side port extends when coupled with the source of diagnostic or therapeutic agent.
16. The assembly of claim 15, wherein:
- said drive means further comprises a drive motor and power supply coupled to said drive motor through a switch that is manually engageable while said drive motor housing is manipulated to rotate said obstruction treatment device drive shaft; and
 - said drive motor unit connector and said obstruction treatment device sub-assembly allow rotation of said obstruction treatment device sub-assembly with respect to said drive motor unit to any selected angular alignment to accommodate the direction that the side port extends when coupled with the source of diagnostic or therapeutic agent and to enable the manipulation of the motor drive housing and operation of the switch.
17. The assembly of claim 16, wherein:
- said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor unit receptacle to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and
 - said obstruction treatment device sub-assembly connector comprises a clip connector further comprising:
 - a clip connector barrel enclosing a clip connector lumen that is axially aligned to the adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said obstruction treatment device sub-assembly connector with said drive motor unit connector; and
 - a moment arm joined by a resilient hinge to the clip connector barrel extending outward of the clip connector barrel, the moment arm extending proximally from said resilient hinge alongside said proximal drive member to a free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat,
 - whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive

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member through said drive motor lumen brings said free clip end into contact with said camming surface to bias said free clip end radially away from said proximal drive member against said resilient hinge until said free clip end engages said annular retention groove and said proximal seat is seated within said drive motor lumen distal end opening, whereupon said obstruction treatment device sub-assembly and said drive motor unit can be rotated with respect to one another as said free clip end traverses and is retained in said annular retention groove.

18. The assembly of claim 17, wherein said clip connector further comprises:

a finger grip formed in a distal extension of said moment arm extending distally from said resilient hinge alongside said barrel, whereby said free clip end can be retracted away and released from said retention groove by depression of said finger grip toward said barrel in order to retract said proximal drive member from said drive motor lumen.

19. The assembly of claim 16, wherein:

said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor lumen distal end opening to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and

said obstruction treatment device sub-assembly connector comprises a clip connector further comprising:

a clip connector barrel enclosing a clip connector lumen that is axially aligned to the Adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said obstruction treatment device sub-assembly connector with said drive motor unit connector; and

a first moment arm joined by a first resilient hinge to the clip connector barrel at a first hinge location extending outward of the clip connector barrel, the first moment arm extending proximally from said first resilient hinge alongside said proximal drive member to a first free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat; and

a second moment arm joined by a second resilient hinge to the clip connector barrel at a second hinge location extending outward of the clip connector barrel disposed at 180° to said first hinge location, the second moment arm extending proximally from said second resilient hinge alongside said proximal drive member to a second free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat,

whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive member through said drive motor lumen brings said first and second free clip ends into contact with said camming surface to bias said first and second free

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clip ends radially away from said proximal drive member against said first resilient hinge until said first and second free clip ends engage said annular retention groove and said proximal seat is seated within said drive motor receptacle surrounding said drive motor lumen distal end opening, whereupon said obstruction treatment device sub-assembly and said drive motor unit can be rotated with respect to one another through as said first and second free clip ends traverse and are retained in said annular retention groove.

20. The assembly of claim 19, wherein said clip connector further comprises:

a first finger grip formed in a distal extension of said first moment arm extending distally from said first resilient hinge along one side of said barrel; and

a second finger grip formed in a distal extension of said second moment arm extending distally from said second resilient hinge along an opposite side of said barrel, whereby said first and second free clip ends can be retracted away and released from said retention groove by depression of said first and second finger grips toward said barrel in order to retract said proximal drive member from said drive motor lumen.

21. The assembly of claim 14, wherein:

said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor lumen distal end opening to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and

said obstruction treatment device sub-assembly connector comprises a clip connector further comprising:

a clip connector barrel enclosing a clip connector lumen that is axially aligned to the adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said obstruction treatment device sub-assembly connector with said drive motor unit connector; and

a moment arm joined by a resilient hinge to the clip connector barrel extending outward of the clip connector barrel, the moment arm extending proximally from said resilient hinge alongside said proximal drive member to a free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat,

whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive member through said drive motor lumen brings said free clip end into contact with said camming surface to bias said free clip end radially away from said proximal drive member against said resilient hinge until said free clip end engages said annular retention groove and said proximal seat is seated against said drive motor unit receptacle surrounding said drive motor lumen distal end opening, whereupon said obstruction treatment device sub-assembly and said

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drive motor unit can be rotated with respect to one another as said free clip end traverses and is retained in said annular retention groove.

22. The assembly of claim 21, wherein said clip connector further comprises:

a finger grip formed in a distal extension of said moment arm extending distally from said resilient hinge alongside said barrel, whereby said free clip end can be retracted away and released from said retention groove by depression of said finger grip toward said barrel in order to retract said proximal drive member from said drive motor lumen.

23. The assembly of claim 14, wherein:

said drive motor unit connector is formed in said drive motor unit housing in relation to said drive motor lumen distal end opening with a camming surface extending away from said drive motor lumen distal end opening to an annular retention groove in said drive motor unit housing located a predetermined distance proximally from said drive motor lumen distal end opening; and

said obstruction treatment device sub-assembly connector comprises a clip connector further comprising:

a clip connector barrel enclosing a clip connector lumen that is axially aligned to the adaptor lumen, the clip connector lumen receiving an intermediate drive shaft section of said drive shaft intermediate said proximal drive member and said distal drive shaft section, said clip connector lumen extending to a proximal end opening thereof within said proximal seat and adapted to be aligned to said drive motor lumen distal end opening upon attachment of said obstruction treatment device sub-assembly connector with said drive motor unit connector; and

a first moment arm joined by a first resilient hinge to the clip connector barrel at a first hinge location extending outward of the clip connector barrel, the first moment arm extending proximally from said first resilient hinge alongside said proximal drive member to a first free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat; and

a second moment arm joined by a second resilient hinge to the clip connector barrel at a second hinge location extending outward of the clip connector barrel disposed at 180° to said first hinge location, the second moment arm extending proximally from said second resilient hinge alongside said proximal drive member to a second free clip end that is turned radially inward toward said proximal drive member and located substantially at said predetermined distance proximal to said proximal annular seat,

whereby insertion of said proximal drive shaft end through said drive motor lumen distal end opening and proximal advancement of said proximal drive member through said drive motor lumen brings said first and second free clip ends into contact with said

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camming surface to bias said first and second free clip ends radially away from said proximal drive member against said first resilient hinge until said first and second free clip ends engage said annular retention groove and said proximal seat is seated within said drive motor unit receptacle surrounding said drive motor lumen distal end opening, whereupon said obstruction treatment device sub-assembly and said drive motor unit can be rotated with respect to one another as said first and second free clip ends traverse and are retained in said annular retention groove.

24. The assembly of claim 23, wherein said clip connector further comprises:

a first finger grip formed in a distal extension of said first moment arm extending distally from said first resilient hinge along one side of said barrel; and

a second finger grip formed in a distal extension of said second moment arm extending distally from said second resilient hinge along an opposite side of said barrel, whereby said first and second free clip ends can be retracted away and released from said retention groove by depression of said first and second finger grips toward said barrel in order to retract said proximal drive member from said drive motor lumen.

25. The assembly of claim 14, wherein:

said drive motor unit connector comprises first and second moment arms that are hinged with respect to said drive motor unit receptacle, said first and second moment arms extending proximally from first and second hinges to first and second finger grips, respectively, and extending to first and second arcuate clips that extend inward into the annular drive motor unit receptacle in the unstressed position of the moment arms;

said obstruction treatment device sub-assembly connector comprises a barrel surrounding a barrel lumen terminating in an enlarged annular proximal seat formed with a distal rim adapted to be engaged by said first and second arcuate clips when said proximal seat is received within said annular receptacle,

whereby said first and second finger grips are adapted to be depressed inward toward the drive motor unit housing to move the arcuate clips outward so that the annular proximal seat can be inserted into the annular proximally extending receptacle and said first and second arcuate clips engage the distal rim on release of the tension applied to said first and second finger grips.

26. The assembly of claim 25, wherein said drive motor unit connector further comprises a resilient O-ring inserted within the annular proximally extending receptacle to provide a resilient seating engagement with the annular proximal seat of the barrel so that the arcuate clips force the annular proximal seat against the O-ring to compress it slightly, and the compressed O-ring tensions the attachment between the arcuate clips and the distal rim.

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